RUTGERS
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OF NEW JERSEY

# eIRB User Manual for Committee Members

Ver. 2.1

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## eIRB Access

The website is available via any Internet connection anytime with a supported browser.

http://eirb.rutgers.edu

### *Confidentiality*

While PHI is typically not included in eIRB studies, there are study designs, ideas, methodology, and other proprietary information for which IRB members are responsible for safeguarding.

Precautions should be taken to protect Rutgers information in eIRB. Please protect this information in the following ways:

- Do not select the "Remember Me" feature of the eIRB log in page from laptop or home computers, as this may compromise the security of confidential information.
- Do not share your eIRB password.
- Do not leave your computer unattended while working in eIRB.
- If possible, do not print the Investigators Brochure, the protocol or other study materials.
- If you do print from eIRB, take precautions to destroy the paper upon completion of your review.

### *Getting Help*

If you have problems, need help, or have questions about eIRB please contact your local IRB office.

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# Designated Reviewer Workflow

eIRB enables IRB members to conduct review of new studies, progress reports, study modifications, continuations and reportable events in an electronic environment that improves record-keeping and reduces environmental impact.

There are three ways that reviewers may access submissions to the IRB:

1) Login to eIRB and view the Inbox

2) Click on the link in email notifications

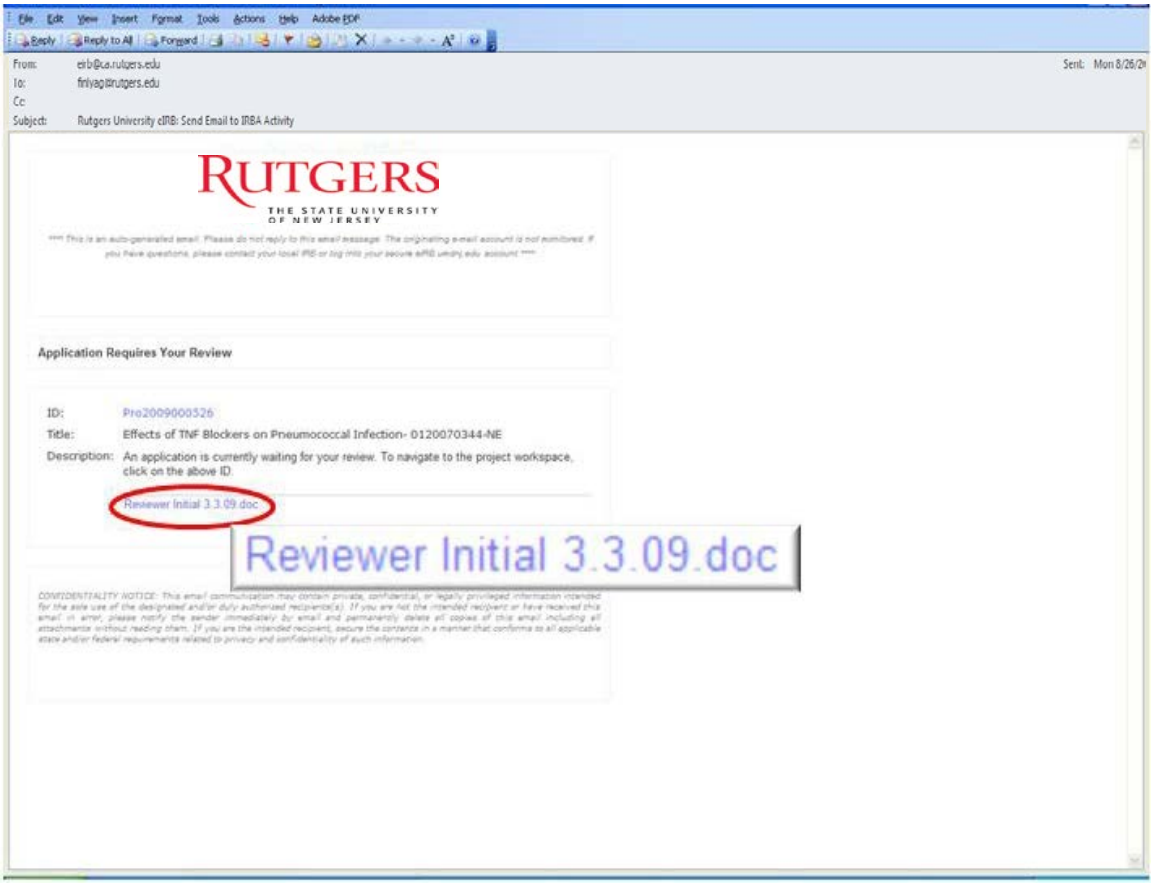
3) Go to the meeting agenda in eIRB

This manual demonstrates the recommended process for designated reviewers:

- Login to eIRB
- Select the submission you wish to review
- Preview the study
- Enter reviewer notes
- Submit your review and upload the reviewer worksheet

## *Email Notifications*

When a study has been assigned for you to review, you will receive an email from eirb@ca.rutgers.edu. The ID will link you to the eIRB Log-In Page and, after you log in, the Study Workspace.


File Edit View Insert Format Tools Actions Help Adobe PDF
Reply Reply to All Forward
From: erb@ca.rutgers.edu
To: finlyag@rutgers.edu
Cc:
Subject: Rutgers University cIRB: Send Email to IRBA Activity
Sent: Mon 8/26/2
RUTGERS
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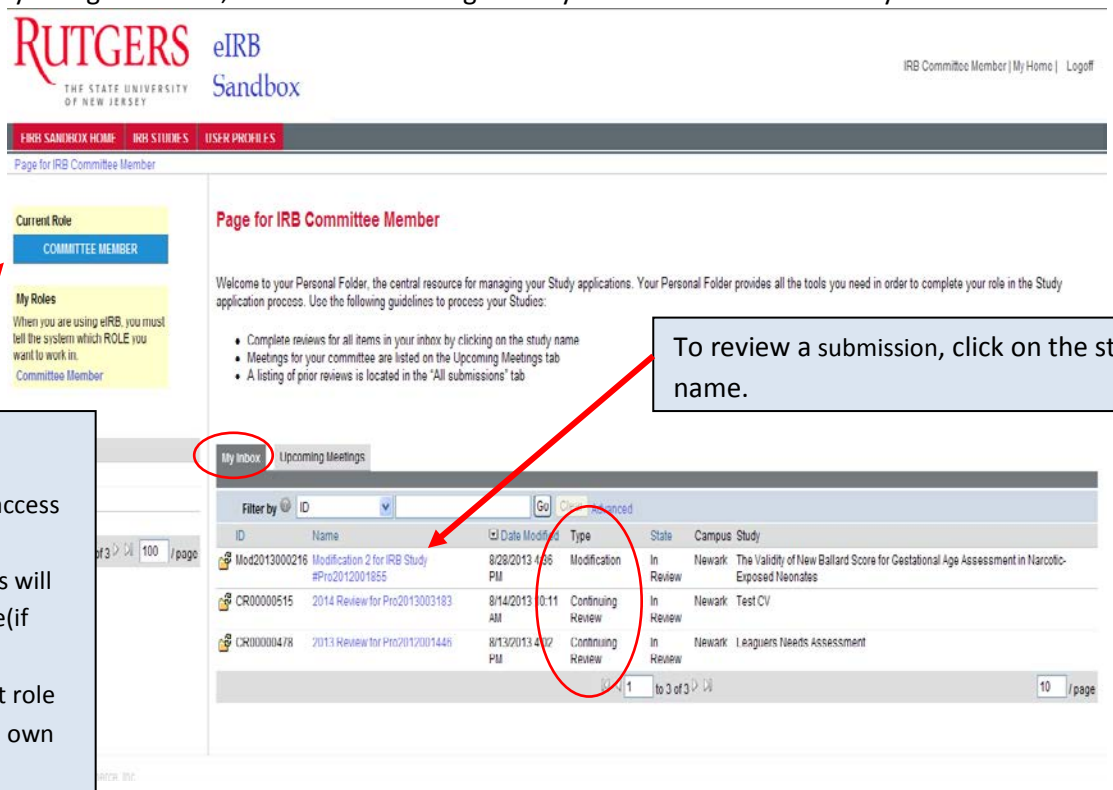
Application Requires Your Review
ID: Pro2009000526
Title: Effects of TNF Blockers on Pneumococcal Infection- 0120070344-NE
Description: An application is currently waiting for your review. To navigate to the project workspace, click on the above ID.
Reviewer Initial 3.3.09.doc
Reviewer Initial 3.3.09.doc

## Personal Workspace: "My Home"

When you log in to eIRB, all submissions assigned to you will be listed under "My Inbox"


RUTGERS
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eIRB
Sandbox
IRB Committee Member | My Home | Logoff
IRB SANDBOX HOME
IRB STUDIES
USER PROFILES
Page for IRB Committee Member
Current Role
COMMITTEE MEMBER
My Roles
When you are using eIRB, you must tell the system which ROLE you want to work in.
Committee Member
Page for IRB Committee Member
Welcome to your Personal Folder, the central resource for managing your Study applications. Your Personal Folder provides all the tools you need in order to complete your role in the Study application process. Use the following guidelines to process your Studies:
Complete reviews for all items in your inbox by clicking on the study name
Meetings for your committee are listed on the Upcoming Meetings tab
A listing of prior reviews is located in the "All submissions" tab
My Inbox
Upcoming Meetings
Filter by ID
Go
ID
Name
Date Modified
Type
State
Campus
Study
Mod2013000216
Modification 2 for IRB Study #Pro2012001855
8/28/2013 4:06 PM
Modification
In Review
Newark
The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates
CR00000515
2014 Review for Pro2013003183
8/14/2013 10:11 AM
Continuing Review
In Review
Newark
Test CV
CR00000478
2013 Review for Pro2012001446
8/13/2013 4:02 PM
Continuing Review
In Review
Newark
Leaguers Needs Assessment
1 to 3 of 3
10 / page

**Current Role**:

- Determines access level
- Multiple roles will be listed here(if applicable)
- Select correct role
- Each role has own inbox

To review a submission, click on the study name.

You can always return to this view by selecting 'My Home' in the upper right-hand corner. Studies requiring your review will appear in 'My Inbox'.

There are four types of submissions:

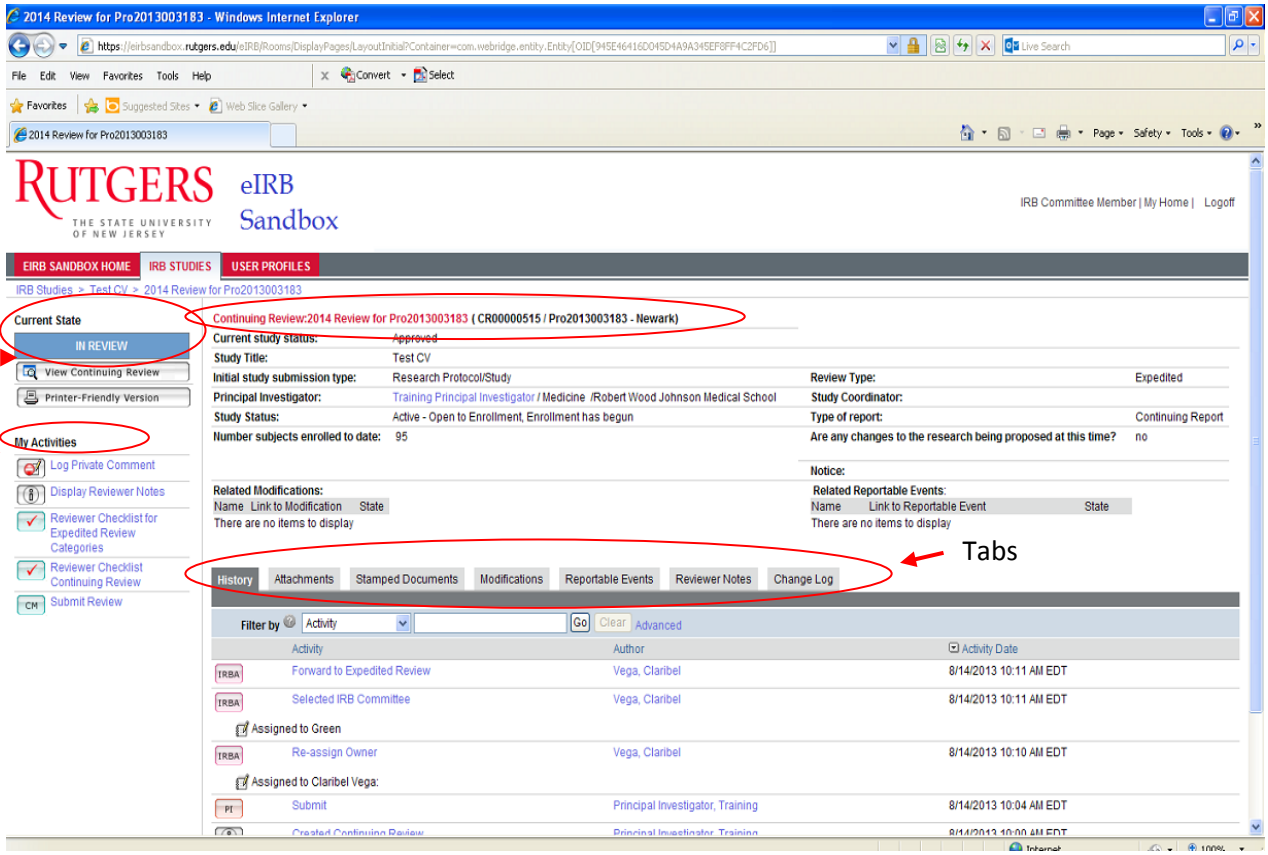
- Initial Submissions- 'Pro'
- Continuing Reviews- 'CR'
- Reportable Events- 'RE'
- Modifications- 'Mod'

# Study Workspace

Each type of submission (new study, continuing review, study modification, and reportable event) will have its own Workspace.

Current State specifies where the study is in the IRB review process

Left Navigation Bar




There are several items that appear in all workspace types:

- The left navigation bar is the white area that appears on the left side of each workspace page
- Activities are available to reviewers in the navigation pane
- A history of all the submission's activities appears under the **History** tab. Other tabs include documents submitted in the project and reviewer notes.

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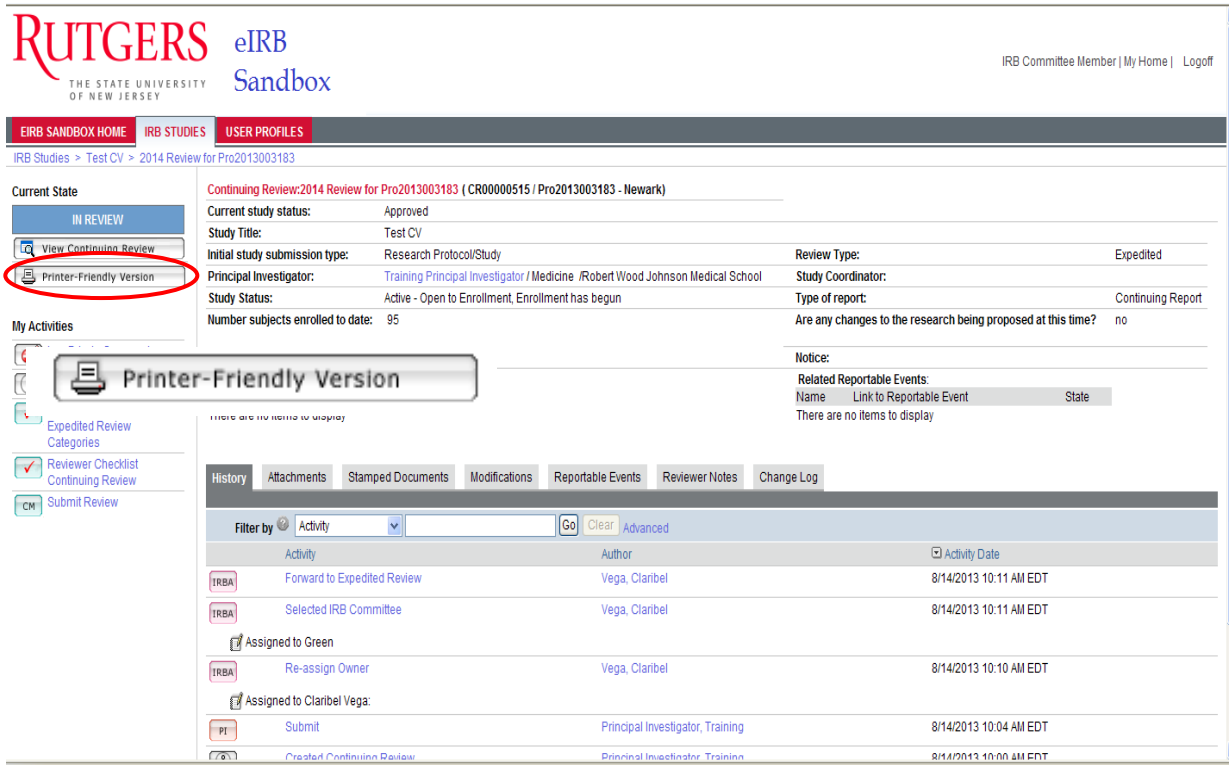
## Reviewing a New Study

To conduct a review in eIRB, you will:

- Preview the study
- Acknowledge or Defer Review
- View the study
- Enter reviewer notes
- Complete required checklist
- Submit the review

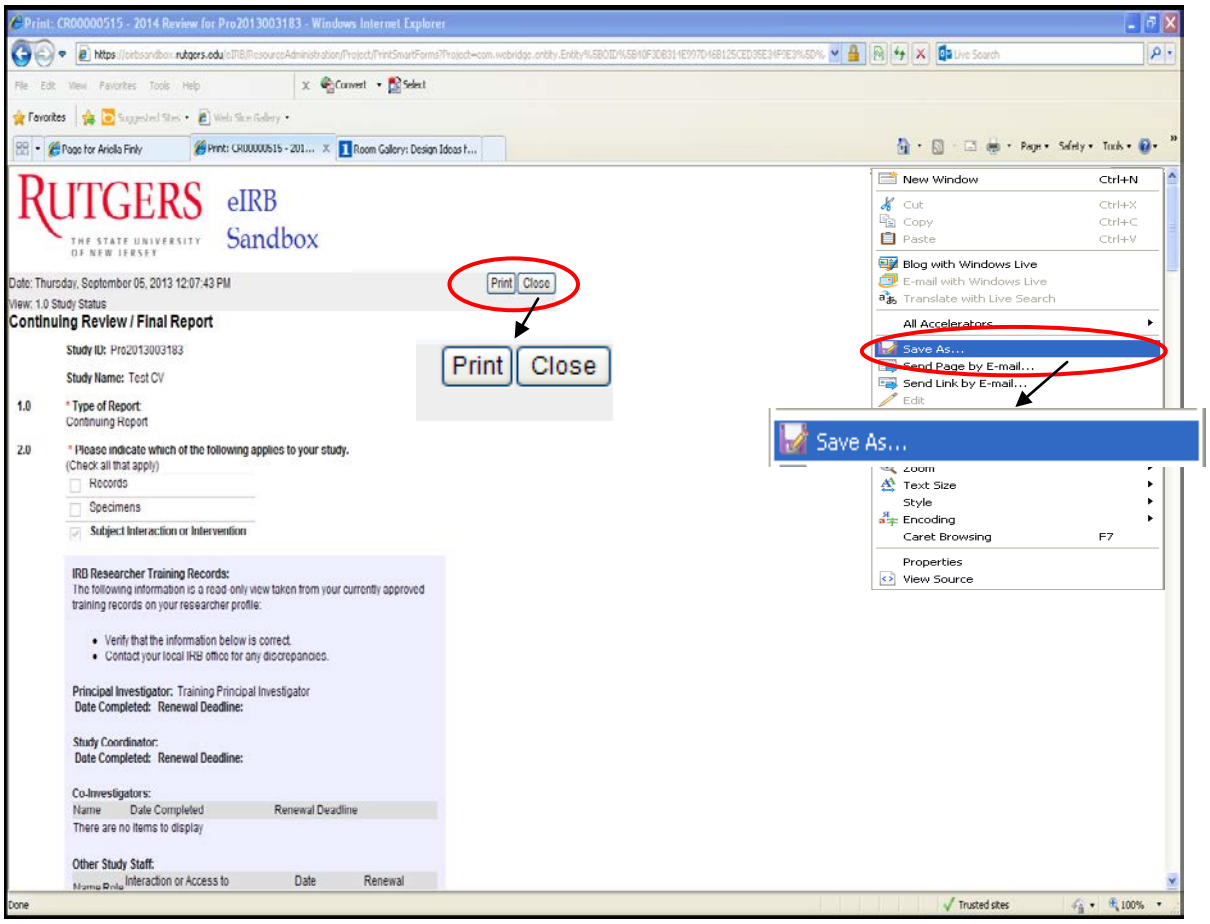
*Preview the study:* A convenient way to preview a study is to click on the 'Printer-Friendly Version' button.



## *Printer Version:*

The printer-friendly version allows reviewers to preview all questions and answers presented to, and answered by, study staff. Additionally, any files uploaded into the form appear as clickable links within the printer-friendly version.

You may print or close the printer friendly version by selecting the two buttons at the top of the page. You may also save the page by selecting 'File' then 'Save As'…in your internet browser.



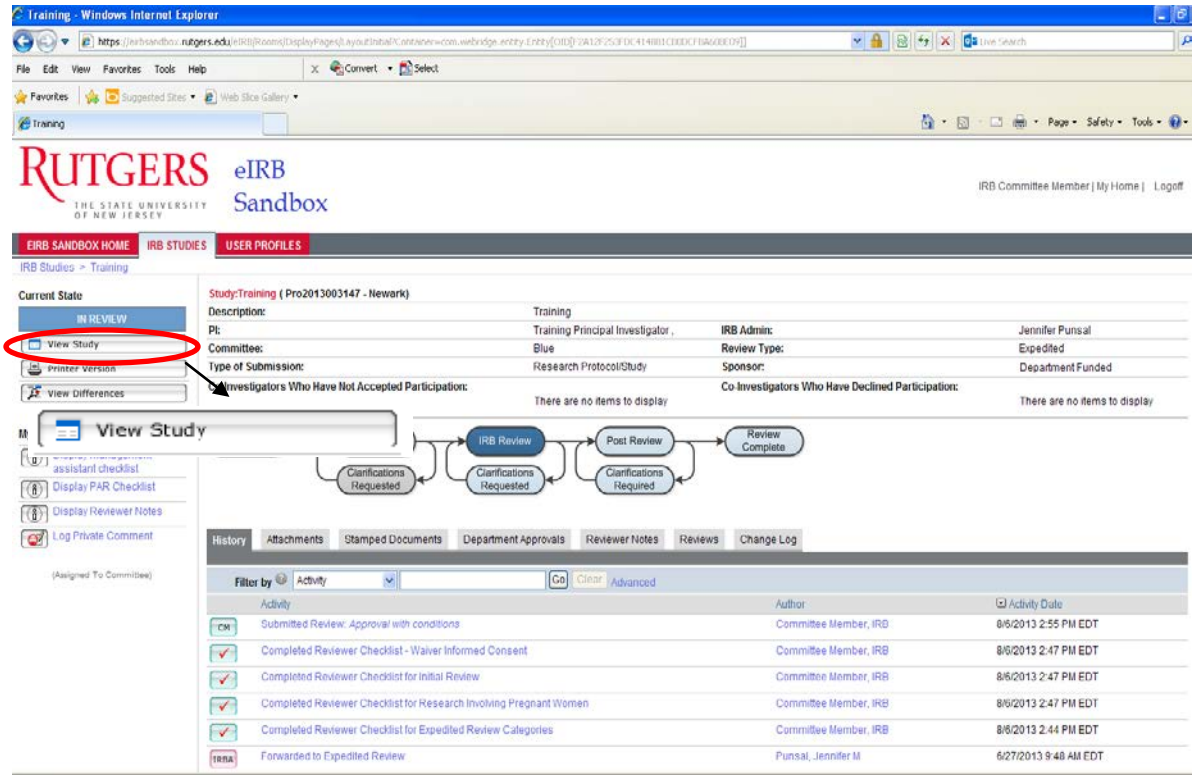
## *Acknowledge Review*

After previewing the printer version of the study, you will decide whether to 'Acknowledge Review or Defer Review' located under My Activities. Once you "Acknowledge Review", you can begin your review. You will want to view the study so that you can enter comments and questions about the study. If you "Defer Review" you may send a comment to the IRB Office noting the reasons for the deferral.

## *Viewing a New Study*

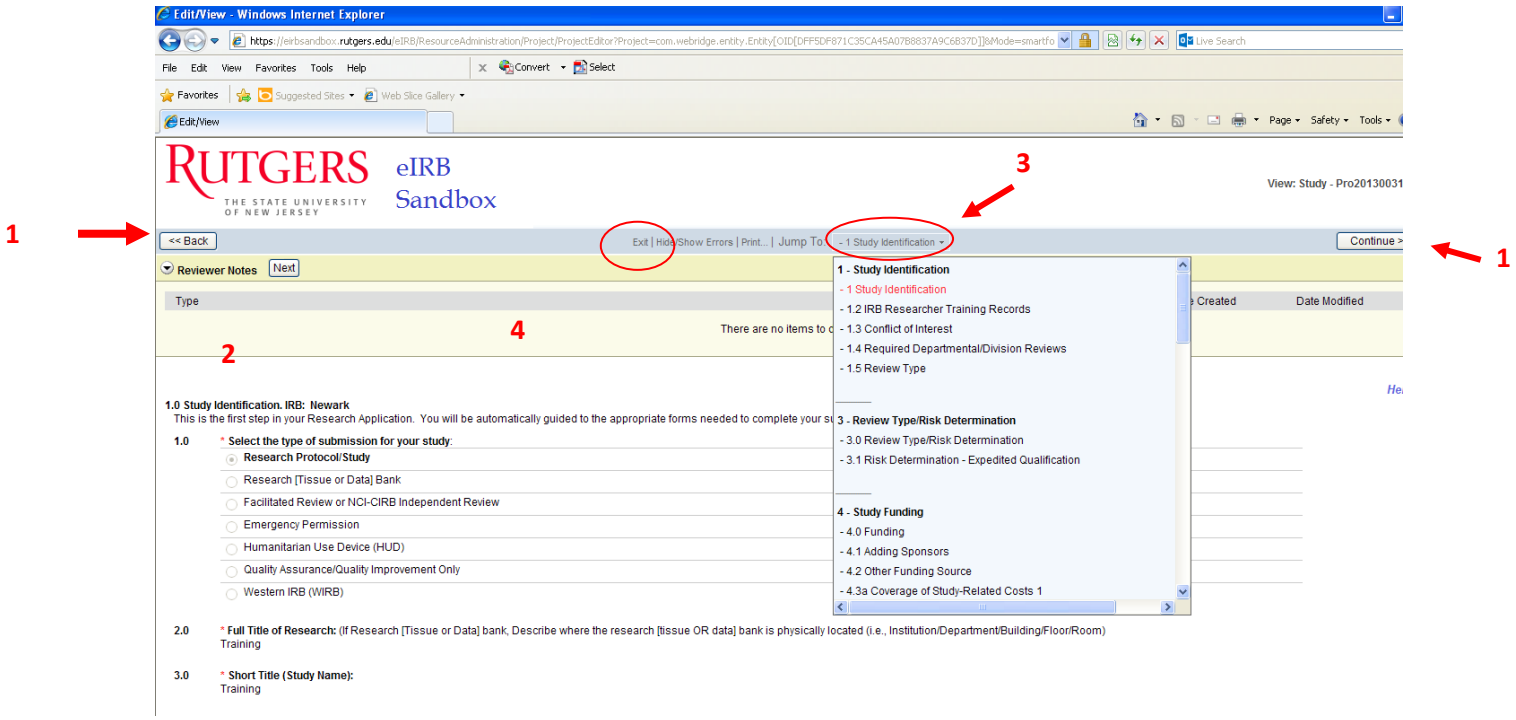
To access the study, select the 'View Study' button.

Once you have selected 'View Study', a window will open containing the smart-form pages completed by the study staff.




Open files uploaded to the project from links with the smart-form view. Attachments can also be found in the 'Attachments' tab in the 'Study Workspace'

## *Study Smart form view:*


1
2
3
4
1
Edit/View - Windows Internet Explorer
RUTGERS
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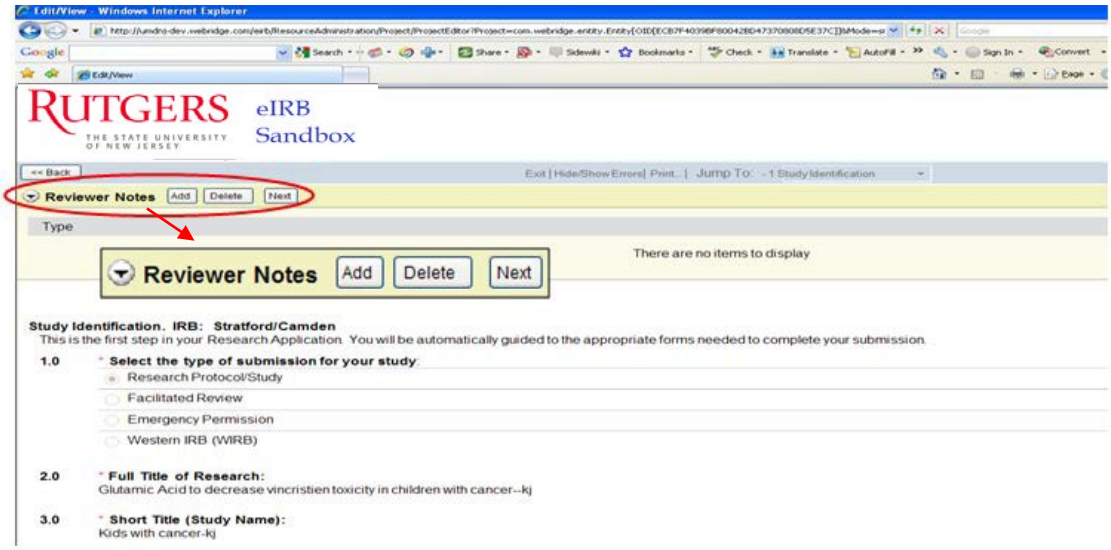
eIRB
Sandbox
<< Back
Exit | Hide/Show Errors | Print... | Jump To
- 1 Study Identification
Continue >
Reviewer Notes
Next
Type
Created
Date Modified
There are no items to
1 - Study Identification
- 1 Study Identification
- 1.2 IRB Researcher Training Records
- 1.3 Conflict of Interest
- 1.4 Required Departmental/Division Reviews
- 1.5 Review Type
3 - Review Type/Risk Determination
- 3.0 Review Type/Risk Determination
- 3.1 Risk Determination - Expedited Qualification
4 - Study Funding
- 4.0 Funding
- 4.1 Adding Sponsors
- 4.2 Other Funding Source
- 4.3a Coverage of Study-Related Costs 1
1.0 Study Identification. IRB: Newark
This is the first step in your Research Application. You will be automatically guided to the appropriate forms needed to complete your
1.0 * Select the type of submission for your study:
Research Protocol/Study
Research [Tissue or Data] Bank
Facilitated Review or NCI-CIRB Independent Review
Emergency Permission
Humanitarian Use Device (HUD)
Quality Assurance/Quality Improvement Only
Western IRB (WIRB)
2.0 * Full Title of Research: (If Research [Tissue or Data] bank, Describe where the research [tissue OR data] bank is physically located (i.e., Institution/Department/Building/Floor/Room)
Training
3.0 * Short Title (Study Name):
Training

From this view, you may:

1. Navigate using the 'Back' or 'Continue' button
2. Add, edit, and delete reviewer notes
3. Use the 'Jump To' menu to select the specific page you wish to see (the name of the page is the link, to the text, 'Jump To')
4. 'Exit' to return to the study workspace

## Adding Reviewer Notes

Reviewer notes are added to each page where the designated reviewer wishes to make comments. These notes will only be viewable by IRB Staff who will finalize them for study staff, and other reviewers.


Edit/View - Windows Internet Explorer
RUTGERS
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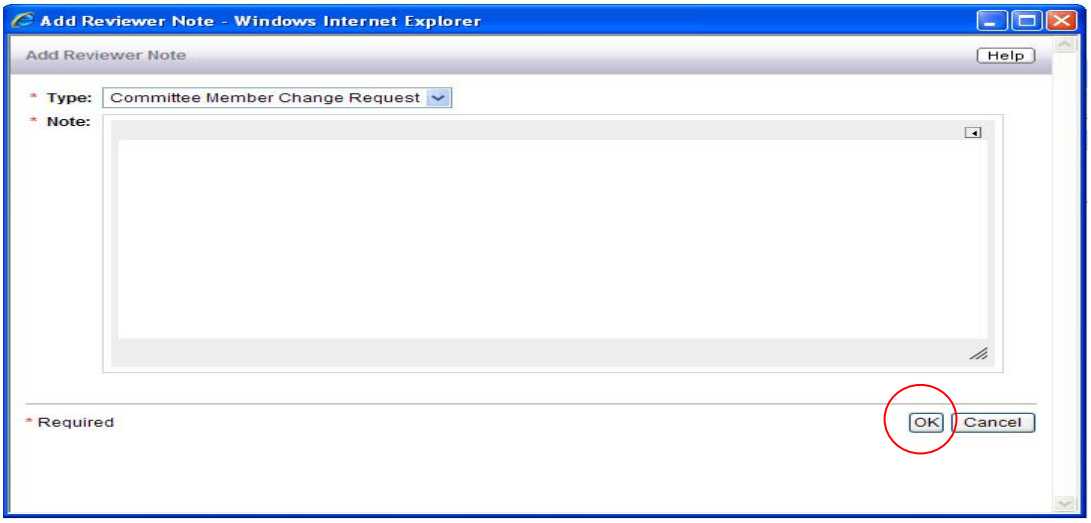
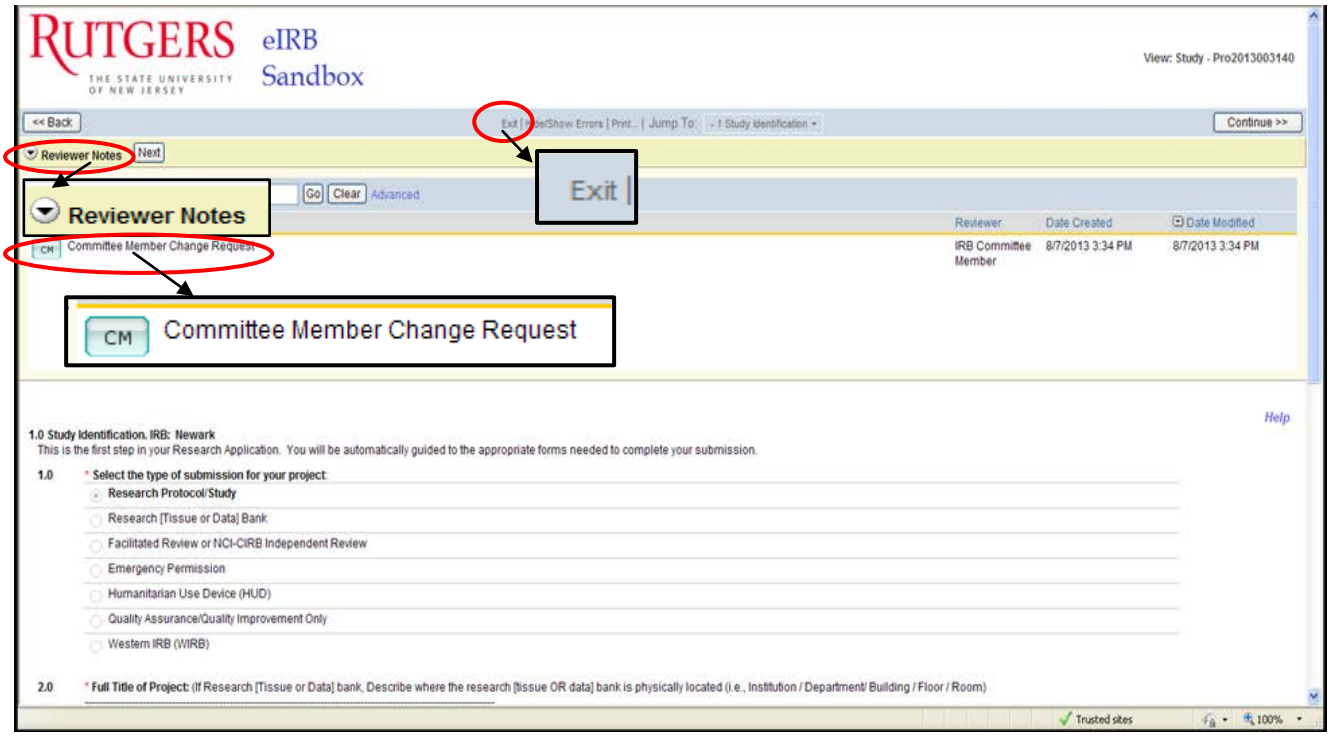
eIRB
Sandbox
Reviewer Notes
Add
Delete
Next
Type
There are no items to display
Study Identification. IRB: Stratford/Camden
This is the first step in your Research Application. You will be automatically guided to the appropriate forms needed to complete your submission.
1.0 * Select the type of submission for your study:
Research Protocol/Study
Facilitated Review
Emergency Permission
Western IRB (WIRB)
2.0 * Full Title of Research:
Glutamic Acid to decrease vincristien toxicity in children with cancer--kj
3.0 * Short Title (Study Name):
Kids with cancer-kj

**To add Reviewer Notes, select 'Add'.**

A new window will open where you will add your comments about the section in question. Click 'OK' after you write your note or 'Cancel' to cancel the activity.



**Note**: Please restrict these notes to the item you would like changed or clarified on a given smart-form page. General comments about the study should be reserved for when you submit your review.


RUTGERS
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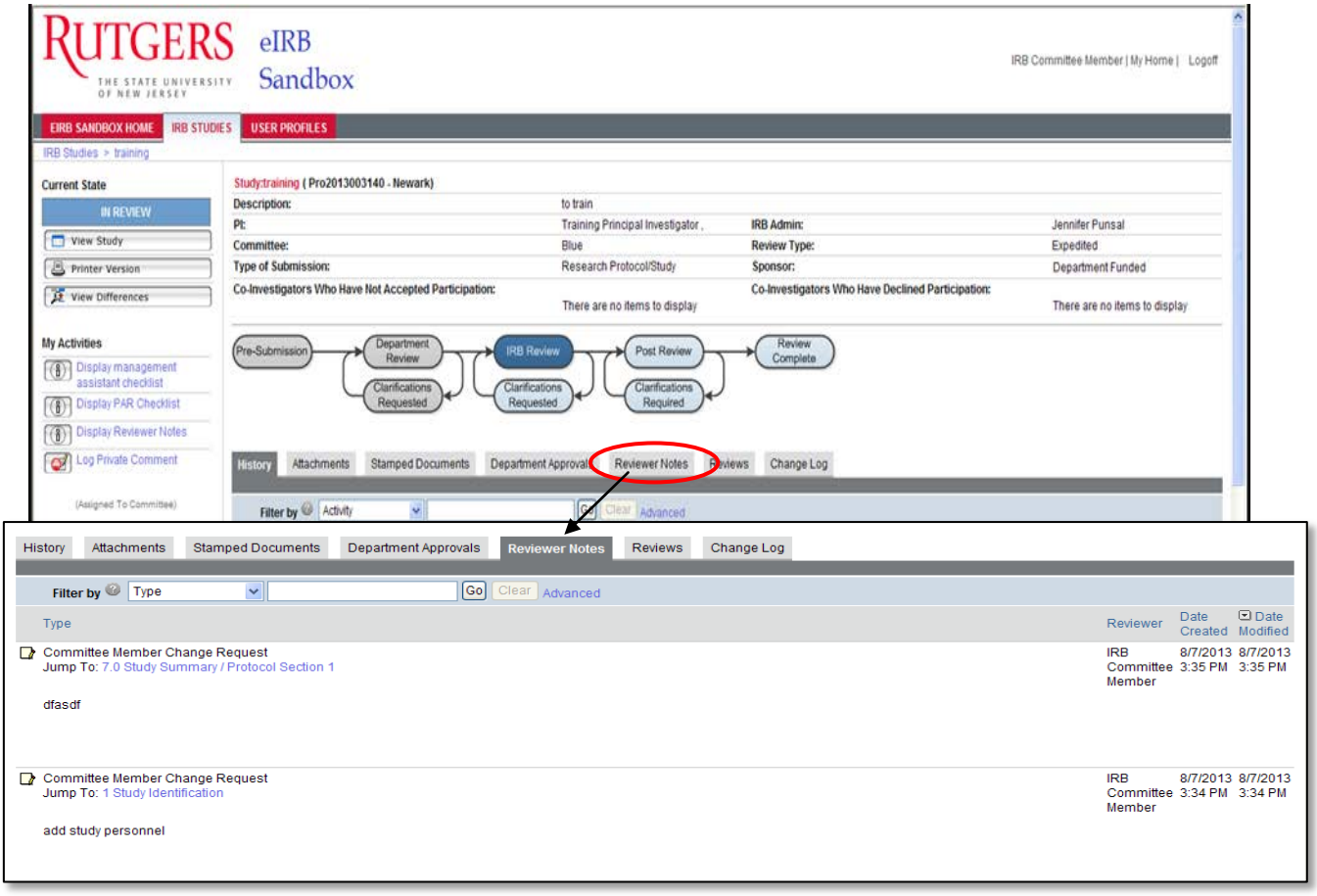
eIRB
Sandbox
View: Study - Pro2013003140
<< Back
Exit
Continue >>
Reviewer Notes
Next
Go
Clear
Advanced
Exit
Reviewer
Date Created
Date Modified
CM
Committee Member Change Request
IRB Committee Member
8/7/2013 3:34 PM
8/7/2013 3:34 PM
Reviewer Notes
CM
Committee Member Change Request
Help
1.0 Study Identification, IRB: Newark
This is the first step in your Research Application. You will be automatically guided to the appropriate forms needed to complete your submission.
1.0 * Select the type of submission for your project:
Research Protocol/Study
Research [Tissue or Data] Bank
Facilitated Review or NCI-CIRB Independent Review
Emergency Permission
Humanitarian Use Device (HUD)
Quality Assurance/Quality Improvement Only
Western IRB (WIRB)
2.0 * Full Title of Project: (If Research [Tissue or Data] bank, Describe where the research [tissue OR data] bank is physically located (i.e., Institution / Department/ Building / Floor / Room)
Trusted sites
100%

Your reviewer note will become visible on the page it is related to by selecting the small black arrow on the left side of the yellow panel.

You may **delete** the note or **add** an additional note. To edit the existing note, click on the link, 'Committee Member Change Request'.

Once you have completed all reviewer notes for each appropriate smart form page, select 'Exit' at the top of the page to return to the 'Study Workspace'.

## *Viewing Reviewer Notes*




A summary of reviewer notes can be viewed from the 'Study Workspace' under the 'Reviewer Notes' tab. Again, these notes will only be visible for IRB staff and other reviewers.

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## *Submitting Your Review*

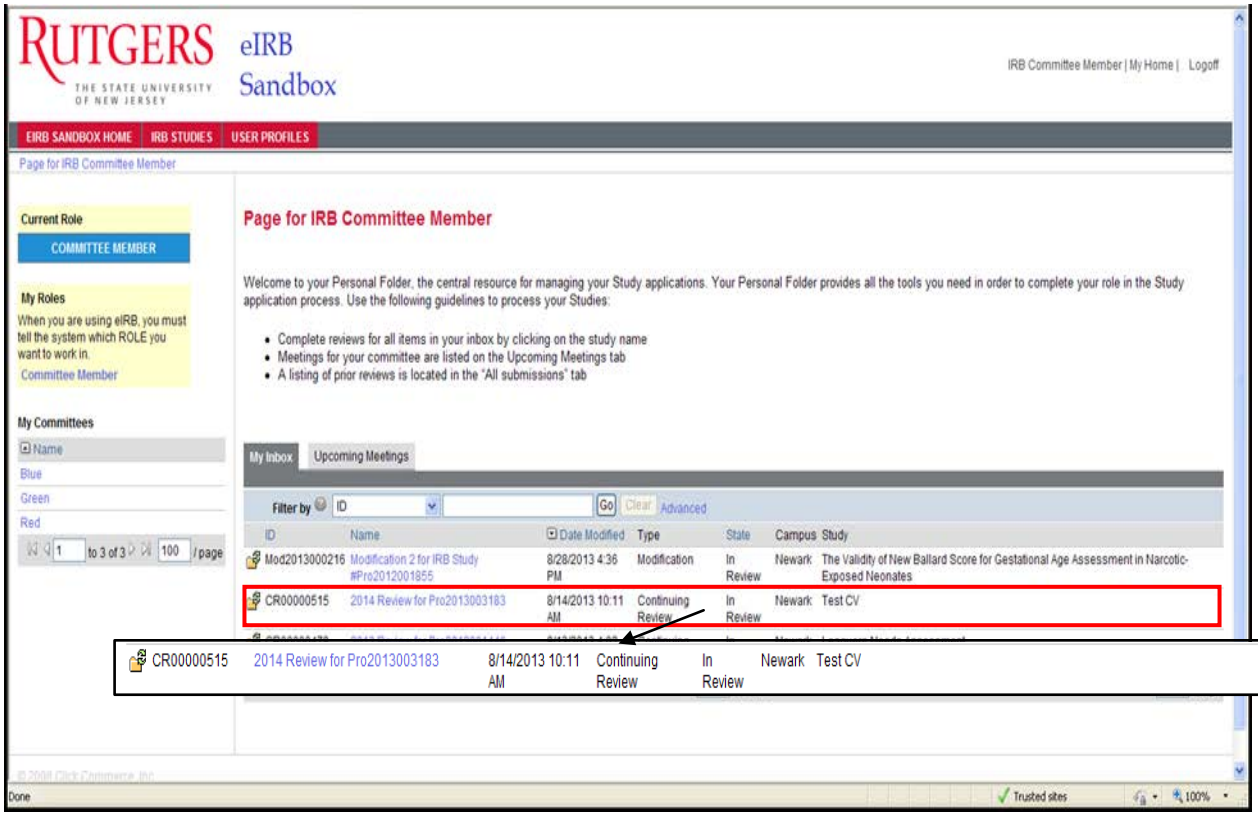
Once you are satisfied with your reviewer notes, you will want to complete the reviewer worksheets.

In order to fill out the Reviewer's Checklist forms, simply click on checklist on the left hand side:

Reviewer Checklist for Exempt Review Categories
Reviewer Checklist for Expedited Review Categories
Reviewer Checklist for Research Involving Pregnant Women
Reviewer Checklist Research Involving Neonates

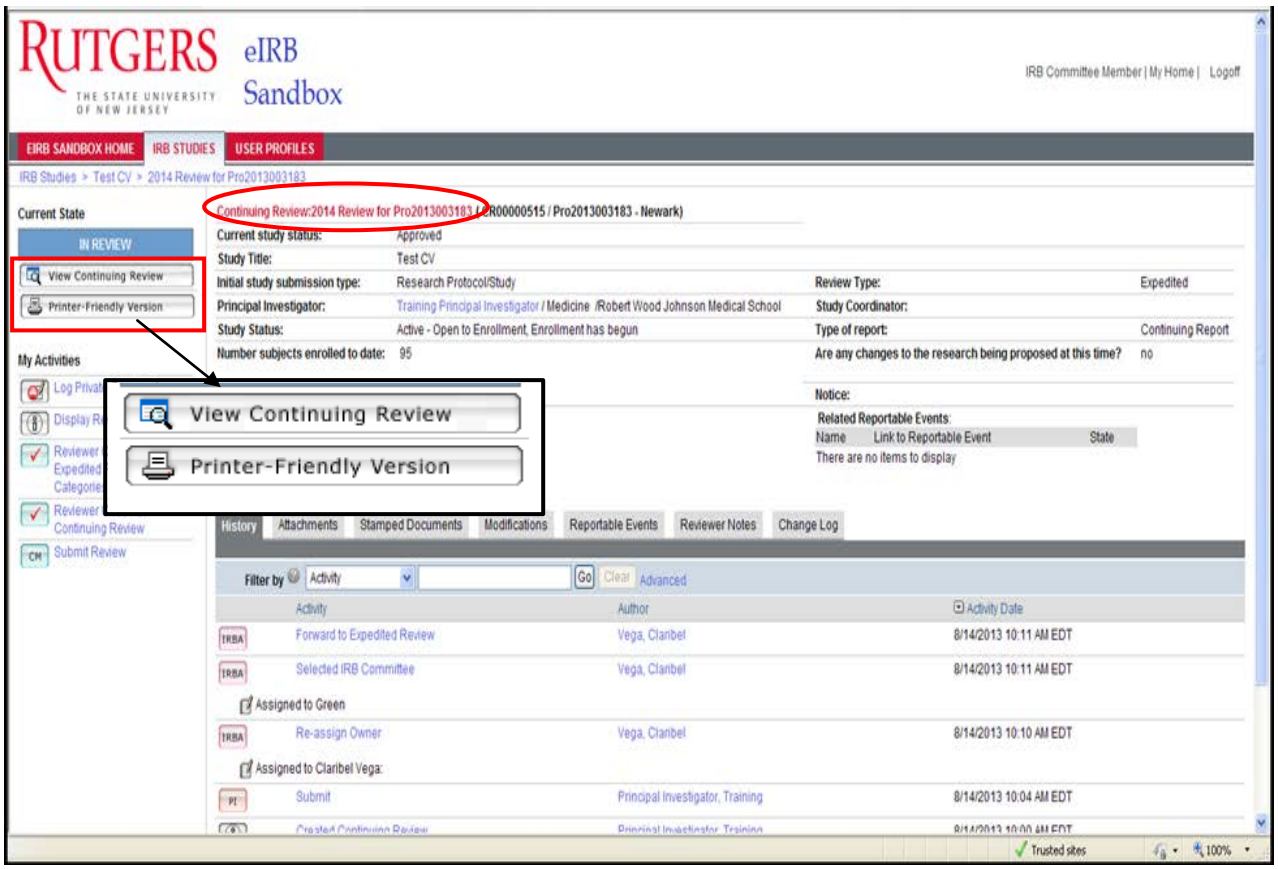
## Reviewing a Continuing Review

To view a study's continuing review workspace, return to 'My Home', select the name of the continuing review listed under 'My Inbox'.

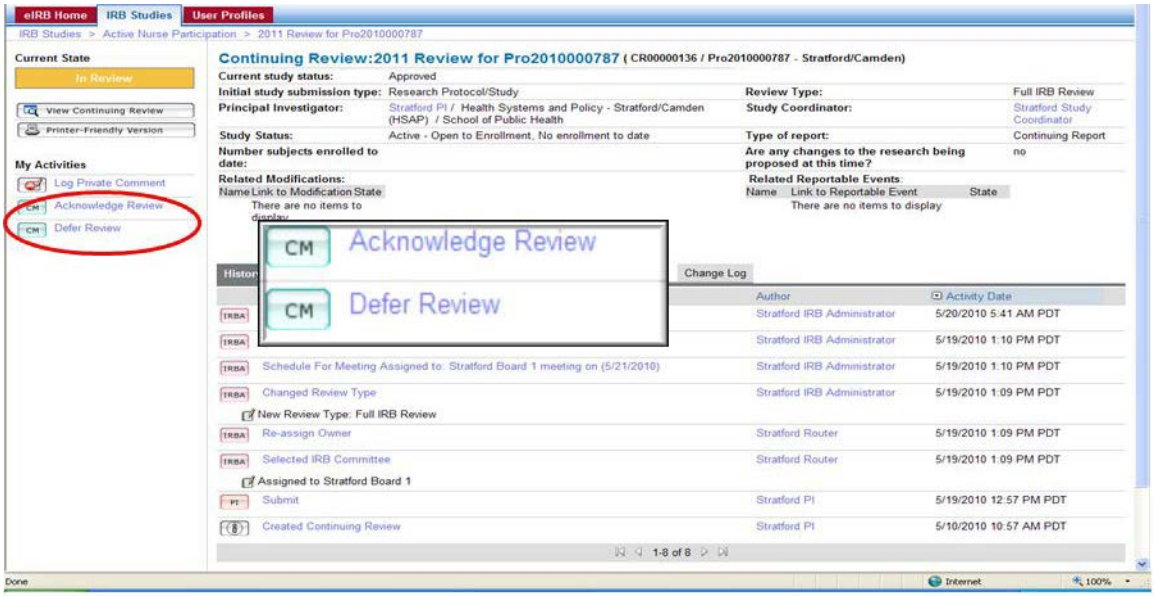



The 'Continuing Review Workspace' is similar to that of a New Submission Review, except that the header information will include a continuing review ID and a description of the continuing review.

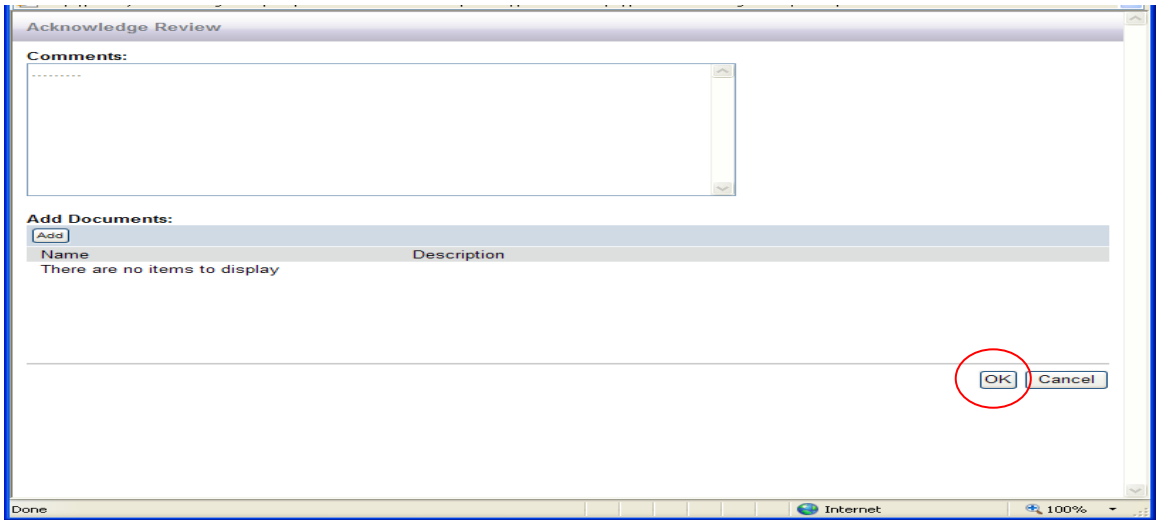
You may open the 'Printer Version' or view the continuing review the same way you view the smart form pages with a new submission, by selecting 'View Continuing Review'.



To begin the review, ‘Acknowledge’ or ‘Defer’ the Continuing Review by clicking the appropriate buttons under ‘My Activities’.


eIRB Home
IRB Studies
User Profiles
Current State
In Review
View Continuing Review
Printer-Friendly Version
My Activities
Log Private Comment
Acknowledge Review
Defer Review
Continuing Review:2011 Review for Pro2010000787 ( CR00000136 / Pro2010000787 - Stratford/Camden)
Current study status: Approved
Initial study submission type: Research Protocol/Study
Review Type: Full IRB Review
Principal Investigator: Stratford PI / Health Systems and Policy - Stratford/Camden (HSAP) / School of Public Health
Study Coordinator: Stratford Study Coordinator
Study Status: Active - Open to Enrollment, No enrollment to date
Type of report: Continuing Report
Number subjects enrolled to date:
Are any changes to the research being proposed at this time? no
Related Modifications:
Name Link to Modification State
There are no items to display
Related Reportable Events:
Name Link to Reportable Event State
There are no items to display
CM Acknowledge Review
CM Defer Review
Change Log
Author
Activity Date
Stratford IRB Administrator 5/20/2010 5:41 AM PDT
Stratford IRB Administrator 5/19/2010 1:10 PM PDT
Schedule For Meeting Assigned to: Stratford Board 1 meeting on (5/21/2010) Stratford IRB Administrator 5/19/2010 1:10 PM PDT
Changed Review Type Stratford IRB Administrator 5/19/2010 1:09 PM PDT
New Review Type: Full IRB Review
Re-assign Owner Stratford Router 5/19/2010 1:09 PM PDT
Selected IRB Committee Stratford Router 5/19/2010 1:09 PM PDT
Assigned to Stratford Board 1
Submit Stratford PI 5/19/2010 12:57 PM PDT
Created Continuing Review Stratford PI 5/10/2010 10:57 AM PDT
1-8 of 8
Done
Internet
100%

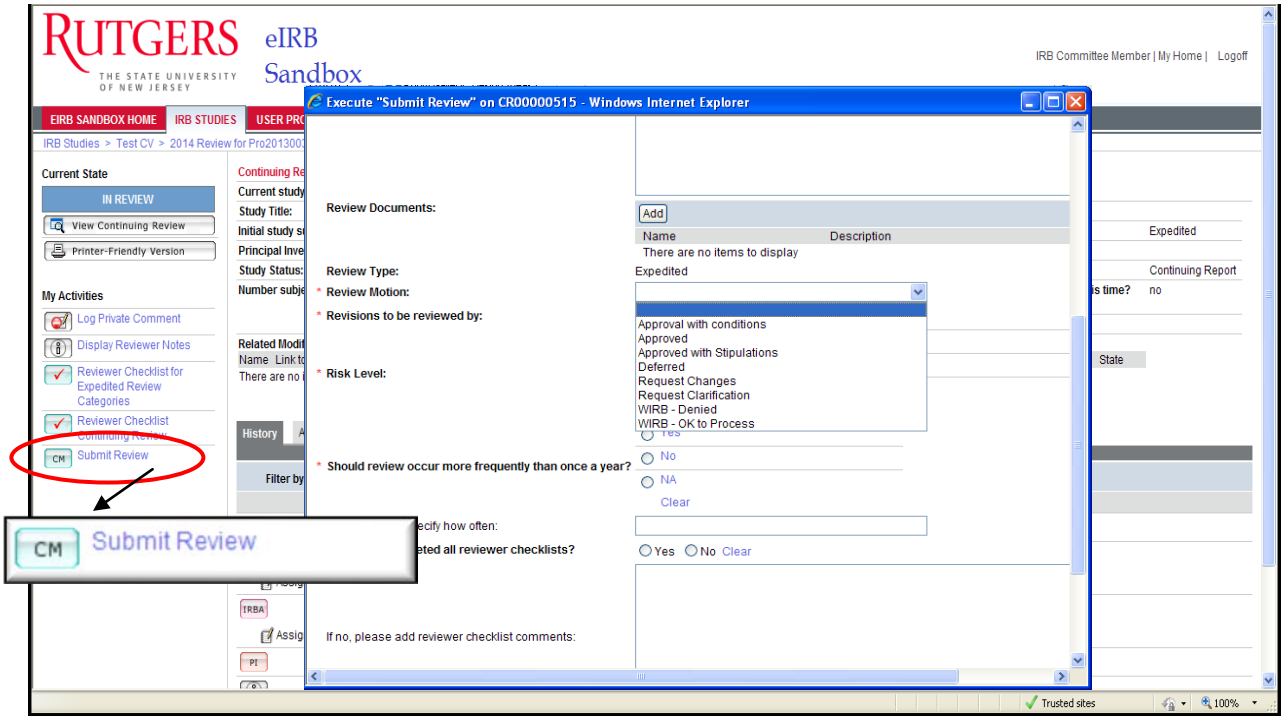
If you ‘Acknowledge’ the continuing review, a box will open allowing you to make comments or add documents. Click ‘OK’ to begin the review process.



When you view the Continuing Review in its smart form version, you can use the '**Jump-to'** menu and add reviewer notes in the same way as a new study.

After you have added all your reviewer notes to the smart-form, exit the study and submit:

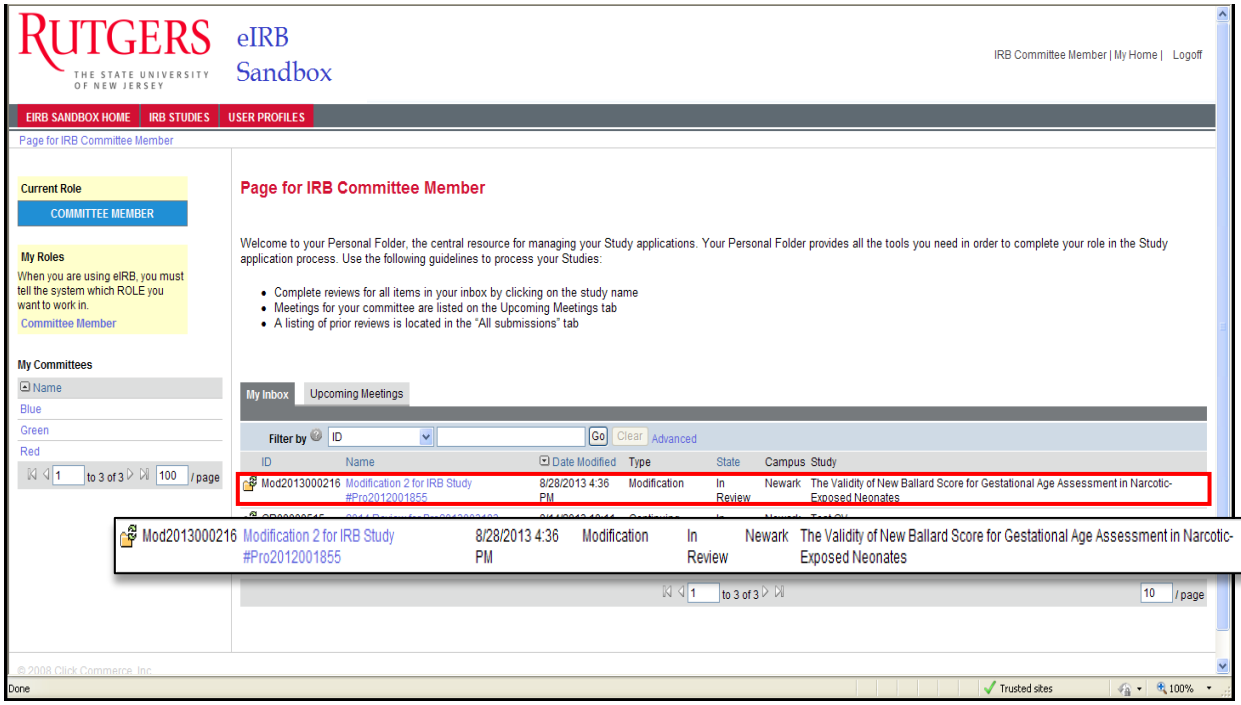
- Any Additional notes
- Add any documents
- Select 'Review Motion'
- Check off 'Review Complete'
- Submit review by selecting 'OK'



## Reviewing a Study Modification

Study modifications are different from other workspace views within eIRB since there are several steps that study staff must take to initiate the activity. Each step in the process has its own workspace; the 'Modification Request' comes first, followed by the changes applied to a 'Modified Study'.

To view the Modification workspace, click the name of the modification listed under 'My Inbox'.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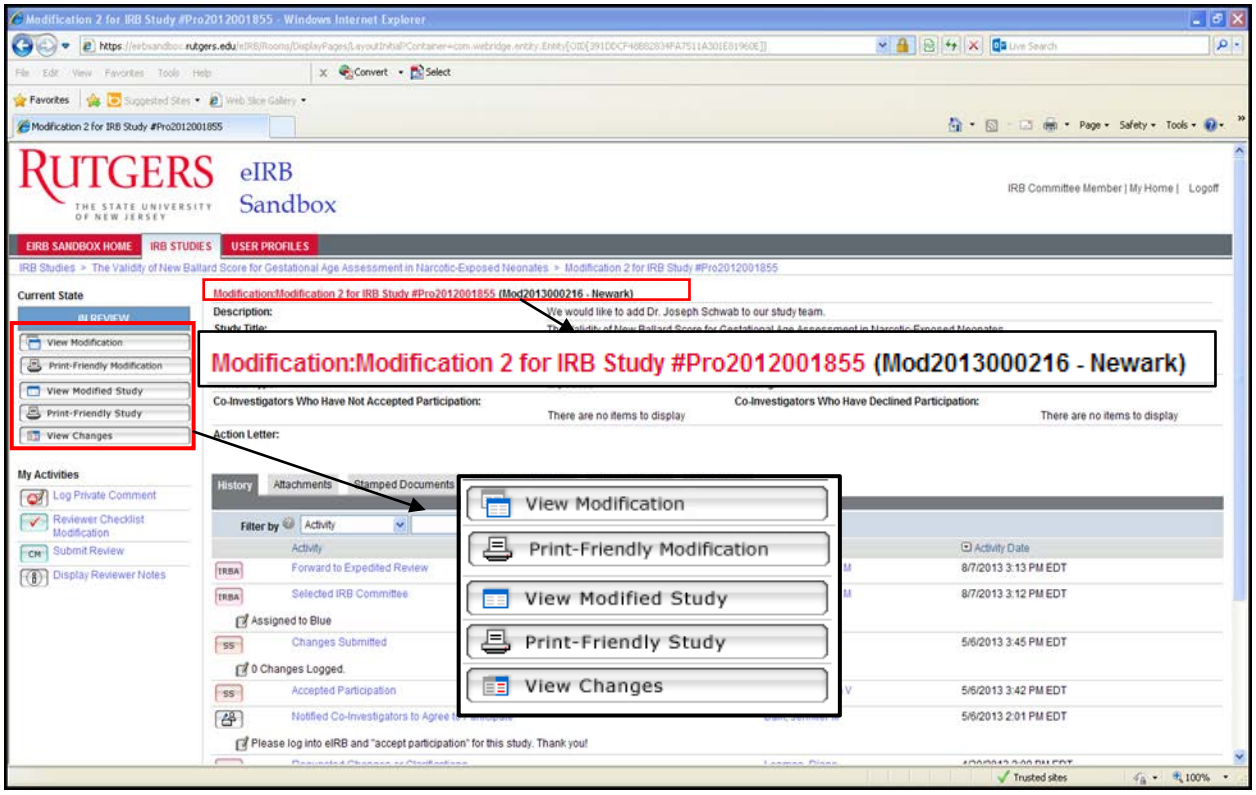
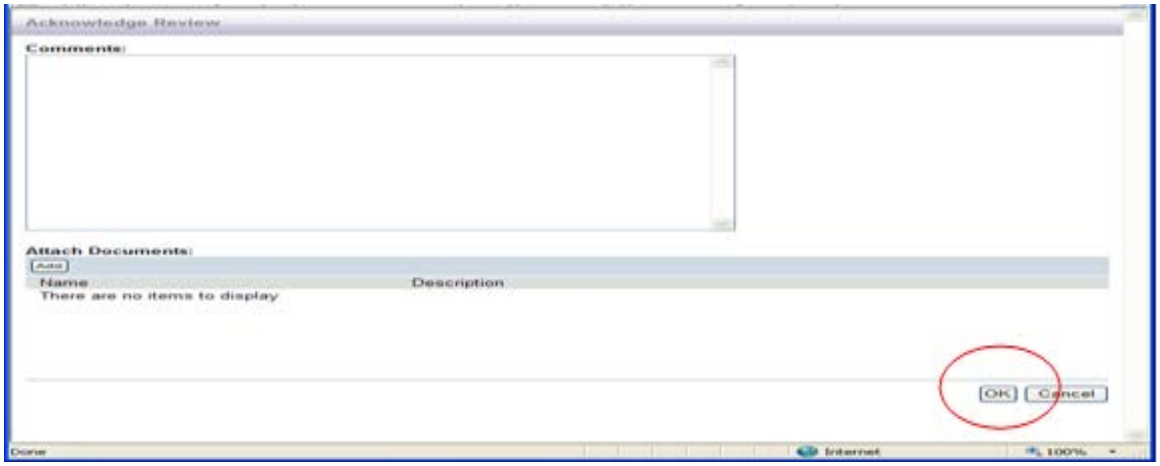
eIRB
Sandbox
IRB Committee Member | My Home | Logoff
EIRB SANDBOX HOME
IRB STUDIES
USER PROFILES
Page for IRB Committee Member
Current Role
COMMITTEE MEMBER
My Roles
When you are using eIRB, you must tell the system which ROLE you want to work in.
Committee Member
My Committees
Name
Blue
Green
Red
Page for IRB Committee Member
Welcome to your Personal Folder, the central resource for managing your Study applications. Your Personal Folder provides all the tools you need in order to complete your role in the Study application process. Use the following guidelines to process your Studies:
Complete reviews for all items in your inbox by clicking on the study name
Meetings for your committee are listed on the Upcoming Meetings tab
A listing of prior reviews is located in the "All submissions" tab
My Inbox
Upcoming Meetings
Filter by
ID
Go
Clear
Advanced
Name
Date Modified
Type
State
Campus
Study
Mod2013000216 Modification 2 for IRB Study #Pro2012001855 8/28/2013 4:36 PM Modification In Review Newark The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates
to 3 of 3
/ page
© 2008 Click Commerce, Inc.
Done
Trusted sites
100%

## *Viewing the Modification Workspace*

The Modification workspace is where study staff initiates the form that describes the proposed changes (the Modification or 'Amendment').

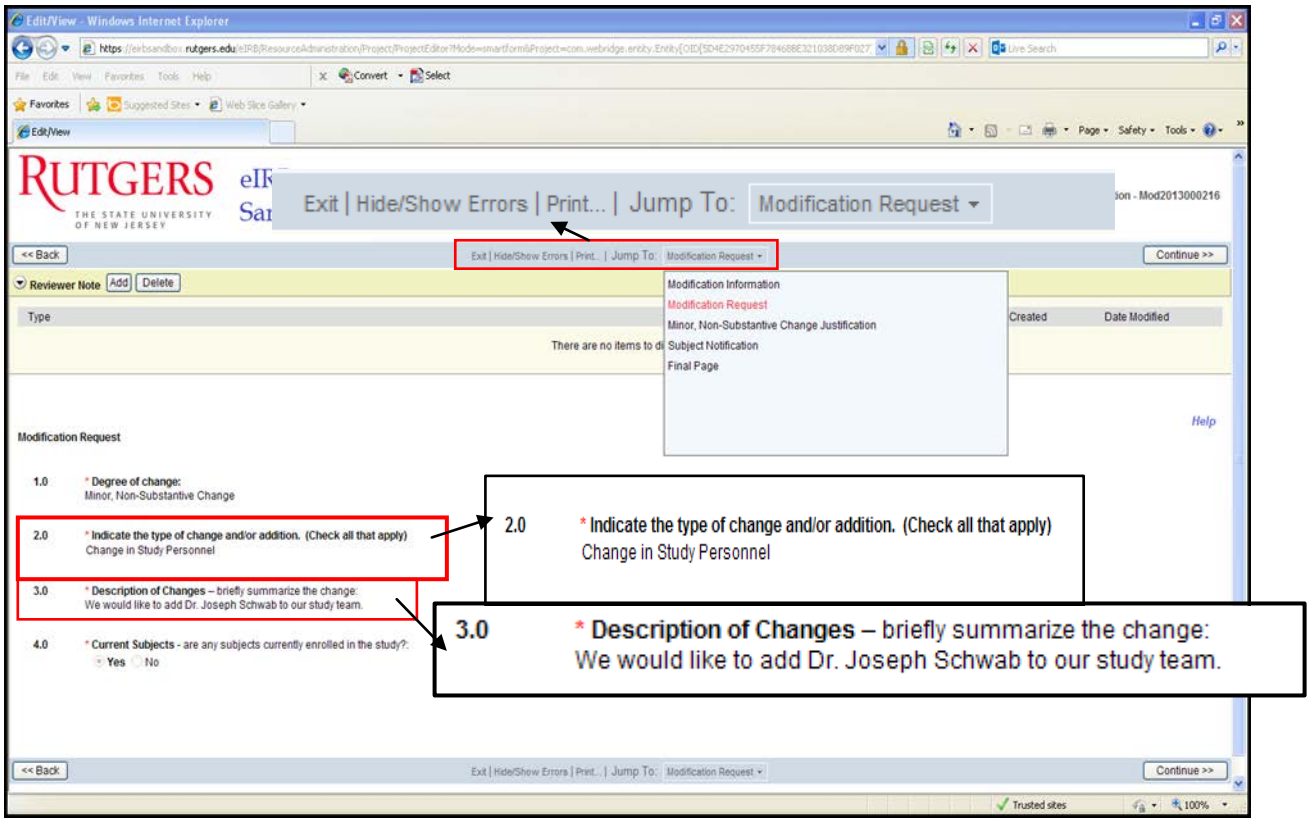



The Modification workspace contains the same 'Printer Version' and header description as a new study. You must '**Acknowledge**' or '**Defer**' the review to begin and click 'OK' in the new window that opens.



## *Viewing the Modification*

Click 'View Modification' to open the Modification smart form. The Modification will contain information about the proposed changes to a study. The actual changes to the study are accessed through 'View Modified Study'.

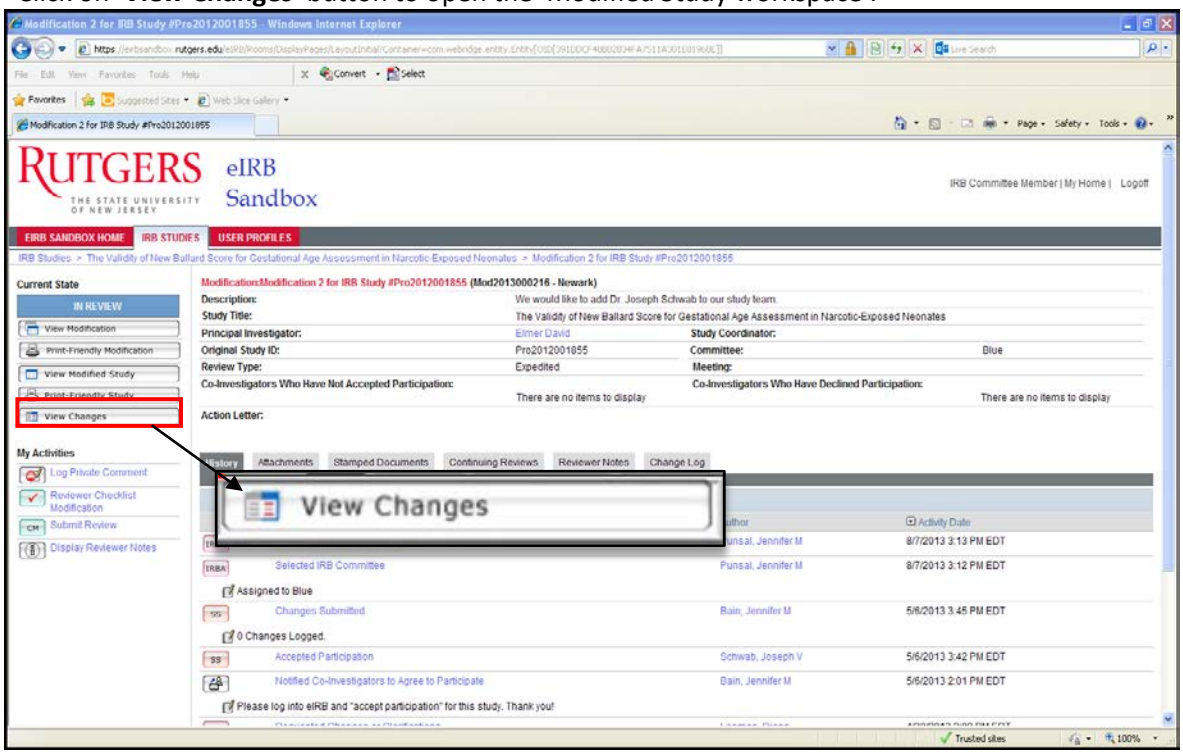

Exit | Hide/Show Errors | Print... | Jump To: Modification Request
Modification Information
Modification Request
Minor, Non-Substantive Change Justification
Subject Notification
Final Page
Modification Request
1.0 * Degree of change: Minor, Non-Substantive Change
2.0 * Indicate the type of change and/or addition. (Check all that apply) Change in Study Personnel
3.0 * Description of Changes – briefly summarize the change: We would like to add Dr. Joseph Schwab to our study team.
4.0 * Current Subjects - are any subjects currently enrolled in the study?: Yes No
2.0 * Indicate the type of change and/or addition. (Check all that apply) Change in Study Personnel
3.0 * Description of Changes – briefly summarize the change: We would like to add Dr. Joseph Schwab to our study team.

Click '**Exit'** to return to the Modification Workspace.

# Modified Study Workspace

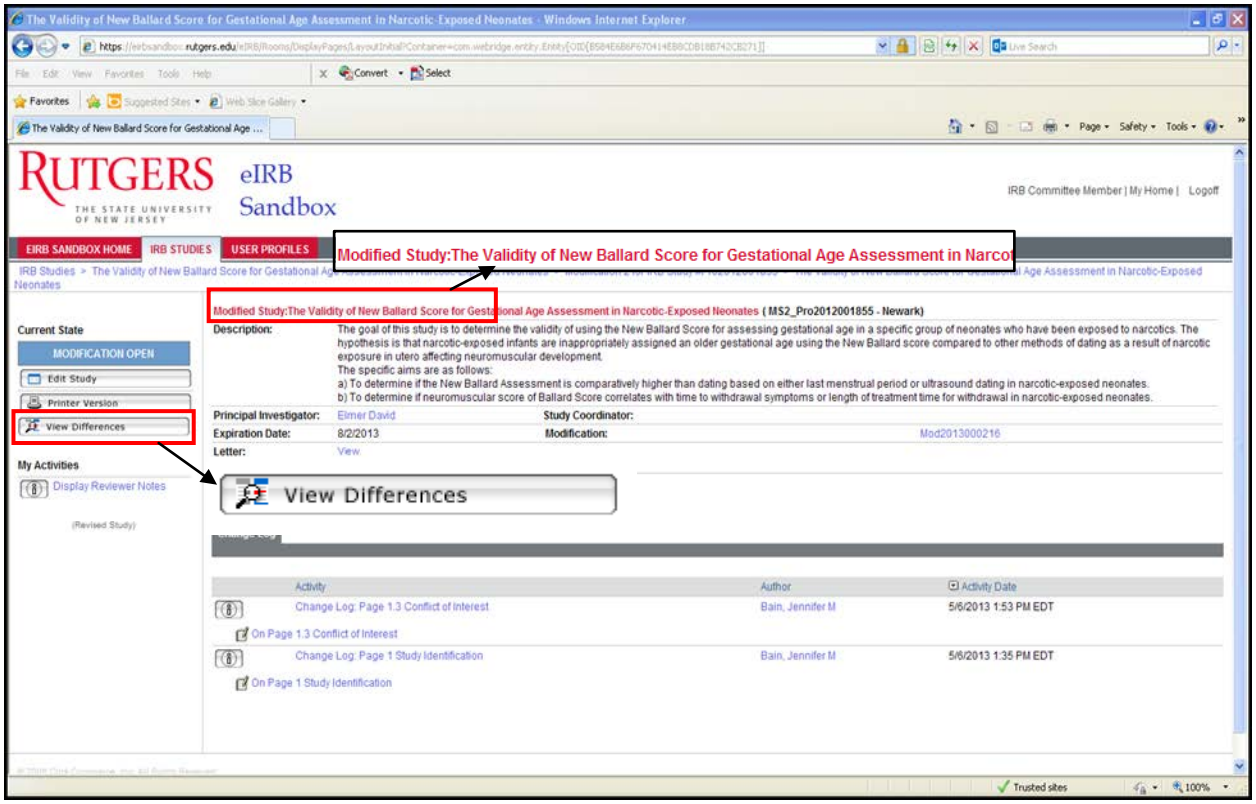
In the Modification workspace,

Click on '**View Changes'** button to open the 'Modified Study workspace'.



## *Modified Study Workspace*

The Modified Study workspace looks similar to the original study workspace; however you'll notice the title says 'Modified Study'.


RUTGERS
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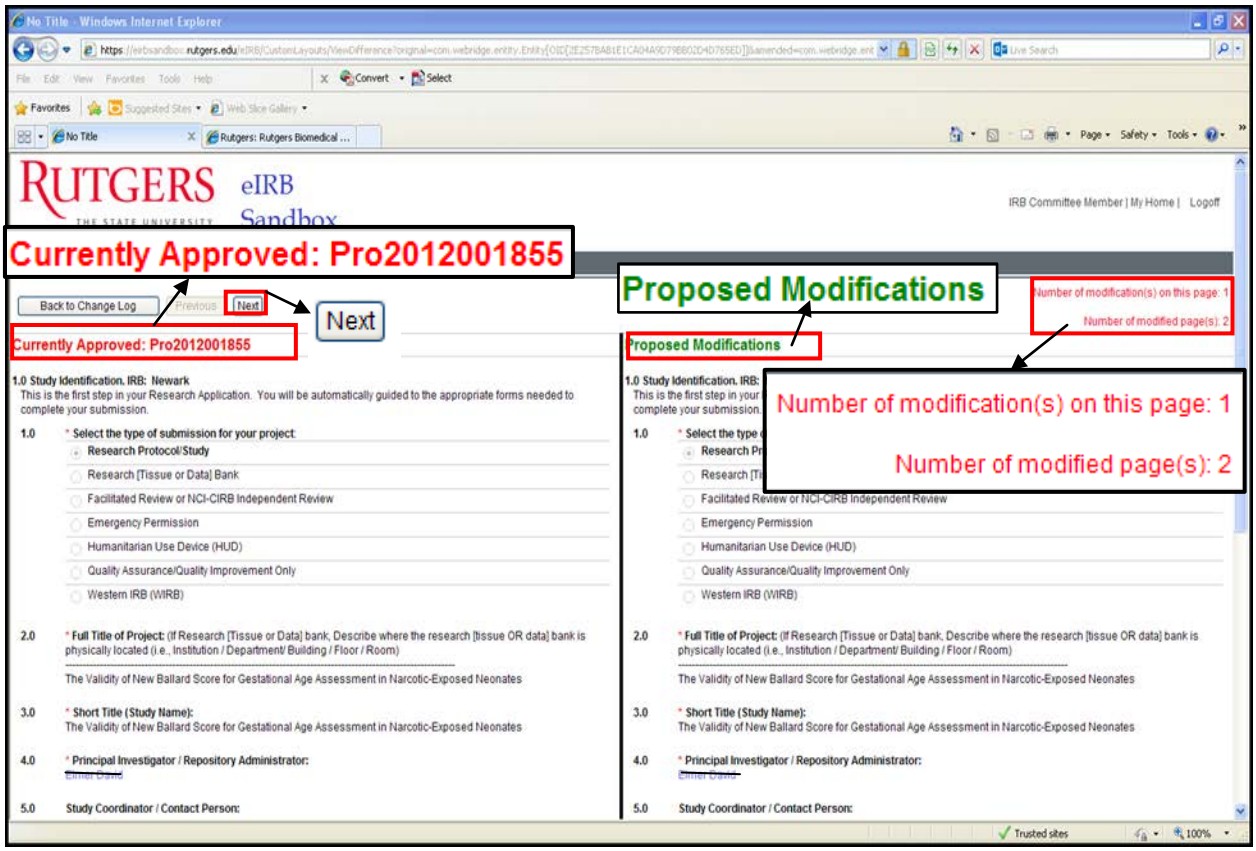
eIRB
Sandbox
IRB Committee Member | My Home | Logoff
EIRB SANDBOX HOME
IRB STUDIES
USER PROFILES
Modified Study:The Validity of New Ballard Score for Gestational Age Assessment in Narcot
Modified Study:The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates ( MS2_Pro2012001855 - Newark)
Current State
MODIFICATION OPEN
Edit Study
Printer Version
View Differences
My Activities
Display Reviewer Notes
Description:
The goal of this study is to determine the validity of using the New Ballard Score for assessing gestational age in a specific group of neonates who have been exposed to narcotics. The hypothesis is that narcotic-exposed infants are inappropriately assigned an older gestational age using the New Ballard score compared to other methods of dating as a result of narcotic exposure in utero affecting neuromuscular development.
The specific aims are as follows:
a) To determine if the New Ballard Assessment is comparatively higher than dating based on either last menstrual period or ultrasound dating in narcotic-exposed neonates.
b) To determine if neuromuscular score of Ballard Score correlates with time to withdrawal symptoms or length of treatment time for withdrawal in narcotic-exposed neonates.
Principal Investigator:
Elmer David
Study Coordinator:
Expiration Date:
8/2/2013
Modification:
Mod2013000216
Letter:
View
View Differences
Activity
Author
Activity Date
Change Log: Page 1.3 Conflict of Interest
Bain, Jennifer M
5/6/2013 1:53 PM EDT
On Page 1.3 Conflict of Interest
Change Log: Page 1 Study Identification
Bain, Jennifer M
5/6/2013 1:35 PM EDT
On Page 1 Study Identification

To see the changes to a study,

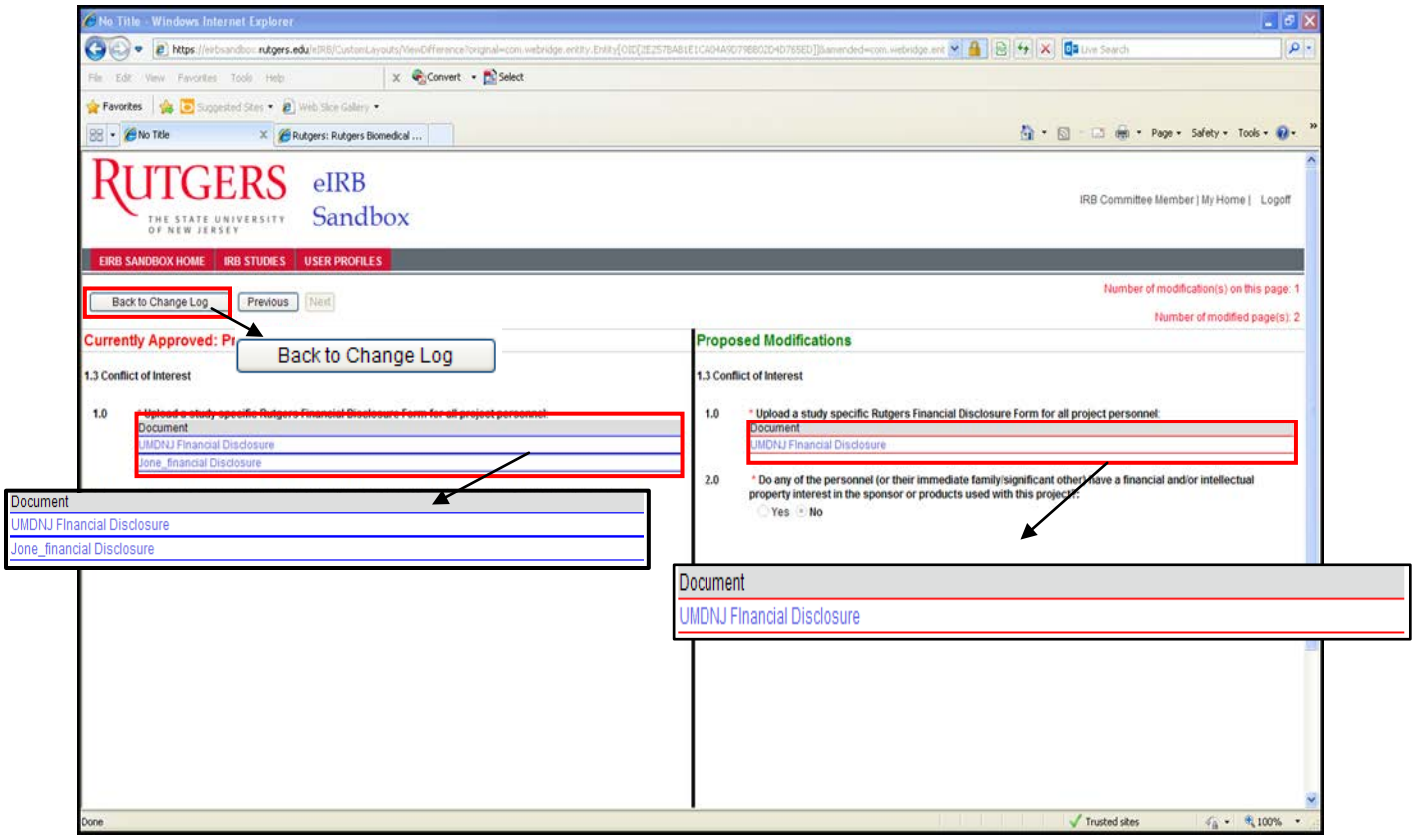
Click on the 'View Differences' button located on the left navigation pane.

## *View Differences*

The View Differences page enables reviewers to easily compare changes made to a study.


Currently Approved: Pro2012001855
Proposed Modifications
Next
Number of modification(s) on this page: 1
Number of modified page(s): 2
Back to Change Log
Previous
Next
Currently Approved: Pro2012001855
Proposed Modifications
1.0 Study Identification, IRB: Newark
This is the first step in your Research Application. You will be automatically guided to the appropriate forms needed to complete your submission.
1.0 * Select the type of submission for your project:
Research Protocol/Study
Research [Tissue or Data] Bank
Facilitated Review or NCI-CIRB Independent Review
Emergency Permission
Humanitarian Use Device (HUD)
Quality Assurance/Quality Improvement Only
Western IRB (WIRB)
2.0 * Full Title of Project: (If Research [Tissue or Data] bank, Describe where the research [tissue OR data] bank is physically located (i.e., Institution / Department/ Building / Floor / Room)
The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates
3.0 * Short Title (Study Name):
The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates
4.0 * Principal Investigator / Repository Administrator:
5.0 Study Coordinator / Contact Person:

The Study Identification page will always appear, regardless of whether there are changes to that page. You will be able to see at a glance the changes on each page in the upper right-hand corner. To navigate to the other revised pages, click 'Next'. You will only see the pages that have been revised.




This page highlights a change in which a revised document was uploaded.

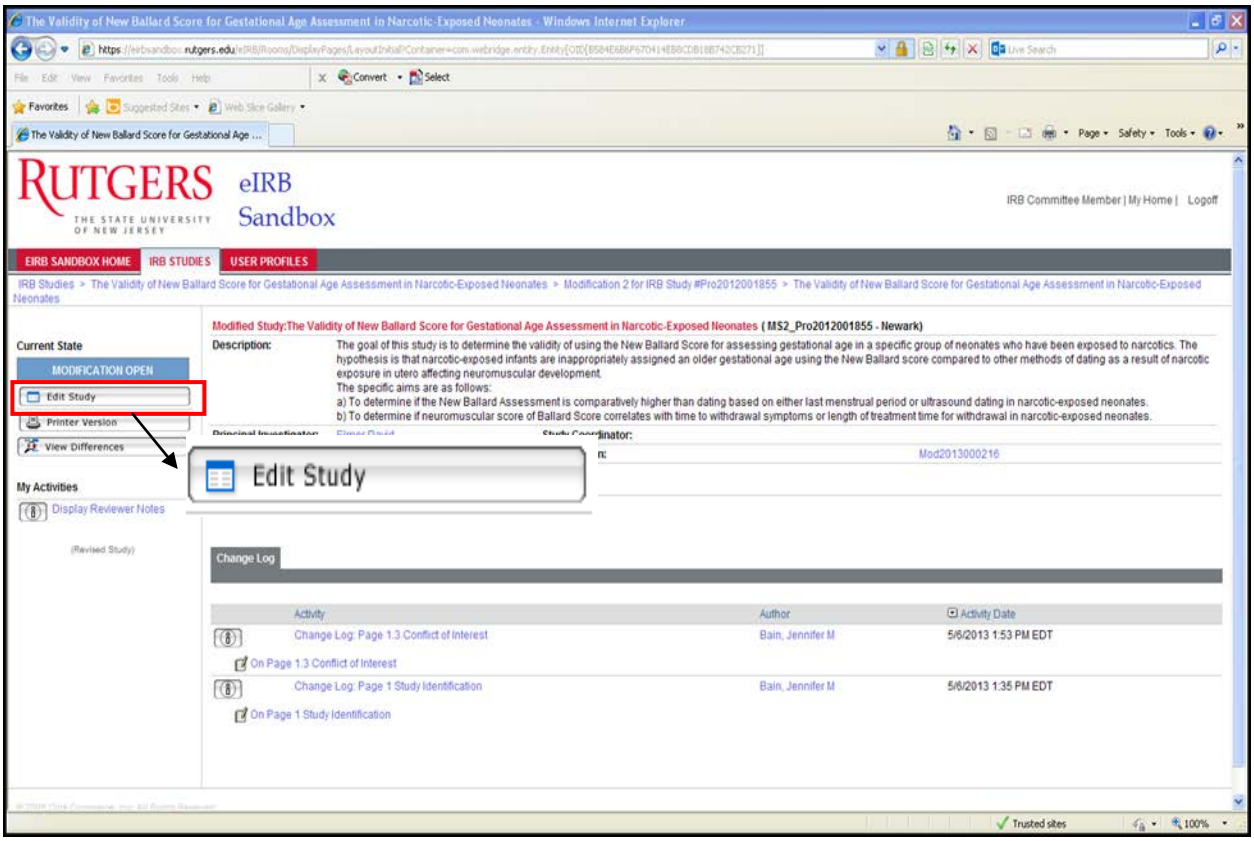
**Note: The view differences feature may show differences in documents and in certain lists that may not always be accurate. If you are unsure about a change, please contact the IRB for clarification.**

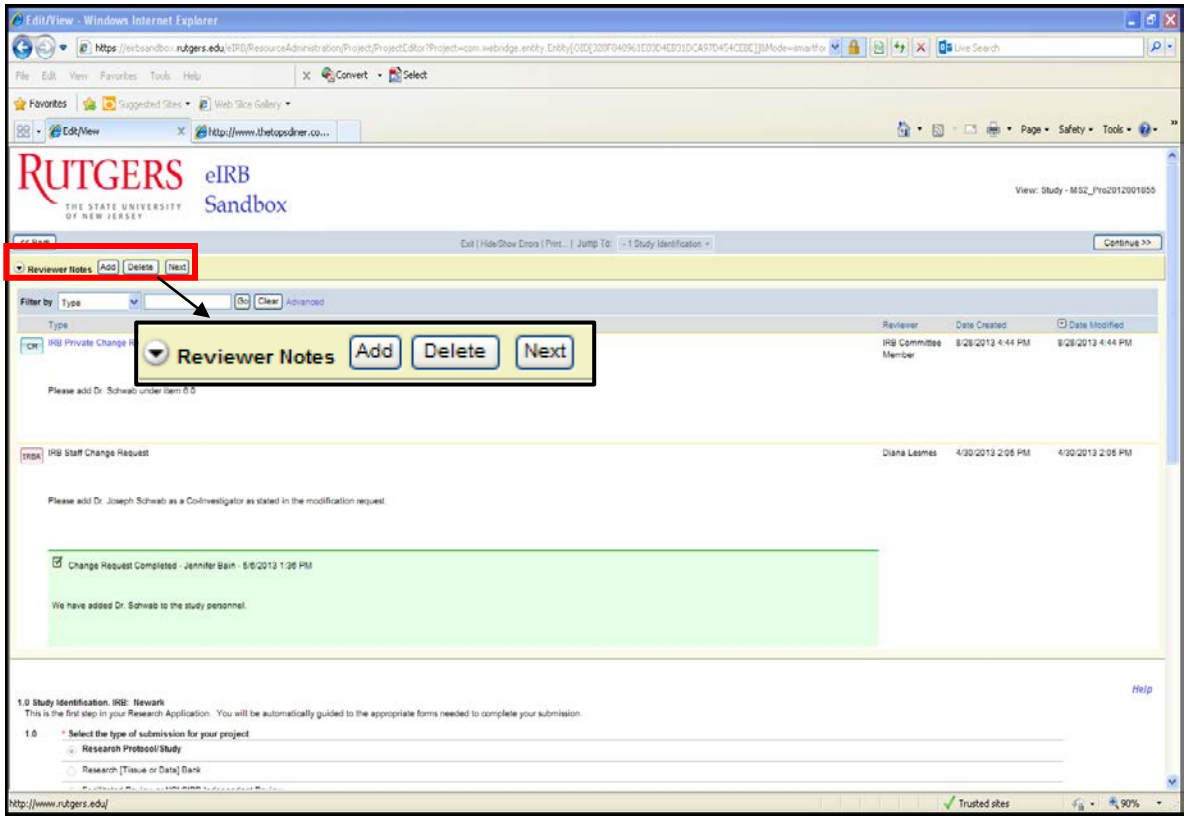
To exit the 'View Differences' application, click the 'Back to Changes Log' button.

## *Viewing the Modified Study*

After you have used the 'View Differences' feature, you may click 'Edit Study' to enter reviewer notes.

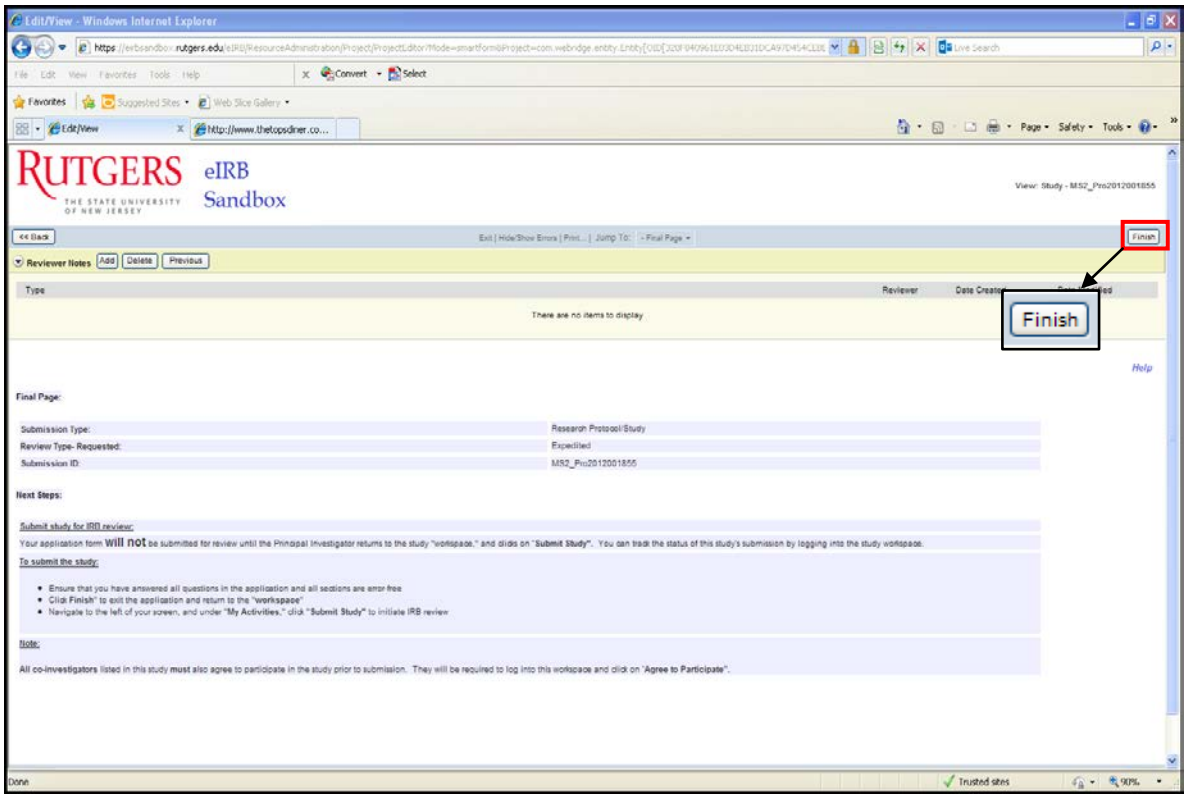
(Note: 'Edit Study' does not actually allow you to edit the study; because the Modified Study workspace is a copy of the original study, it appears identical.)






The 'Modified Study' is a copy of the originally approved study. The reviewer notes work the same way in this view as the previous submission examples.

After you enter your reviewer notes and continue through the entire smart-form application, you will end at the 'Final Page' of the Modified Study. To return to the 'Modified Study Workspace', select *Finish.*


Edit/View - Windows Internet Explorer
RUTGERS
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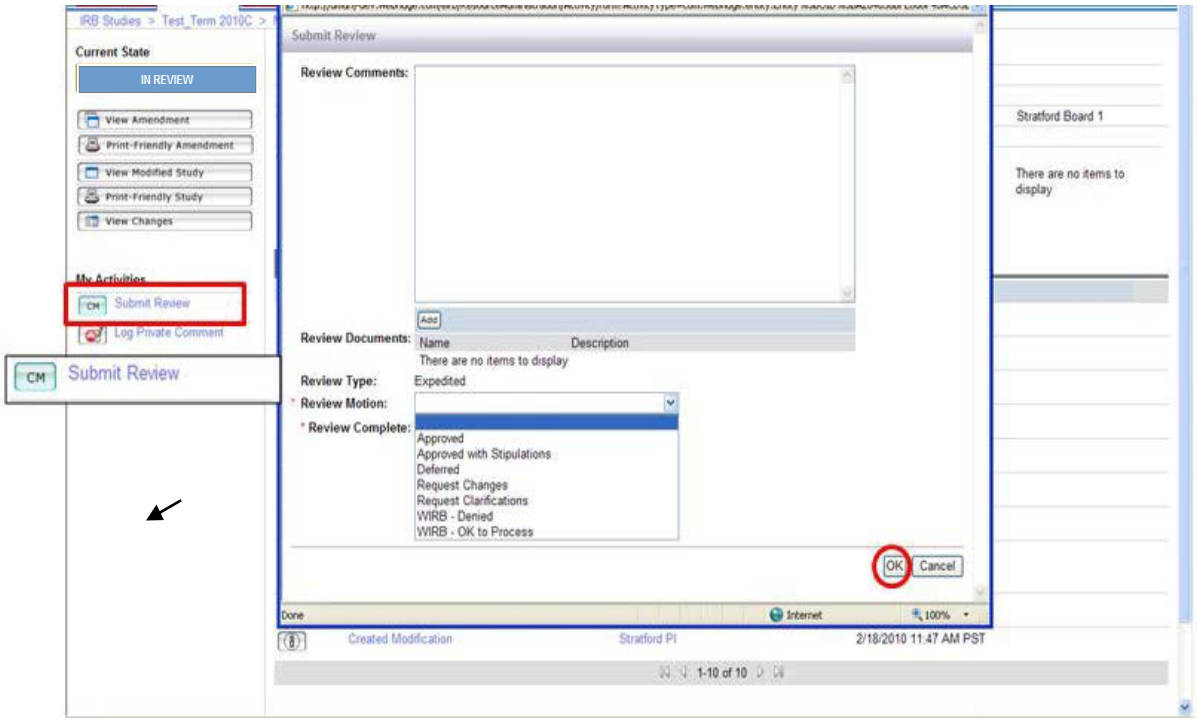
eIRB
Sandbox
<< Back
Finish
Reviewer Notes
Add
Delete
Previous
Type
Reviewer
There are no items to display
Finish
Help
Final Page:
Submission Type:
Research Protocol/Study
Review Type- Requested:
Expedited
Submission ID:
Next Steps:
Submit study for IRB review:
Your application form will not be submitted for review until the Principal Investigator returns to the study "workspace," and clicks on "Submit Study". You can track the status of this study's submission by logging into the study workspace.
To submit the study:
Ensure that you have answered all questions in the application and all sections are error free
Click Finish" to exit the application and return to the "workspace"
Navigate to the left of your screen, and under "My Activities," click "Submit Study" to initiate IRB review
Note:
All co-investigators listed in this study must also agree to participate in the study prior to submission. They will be required to log into this workspace and click on "Agree to Participate".
Done
Trusted sites

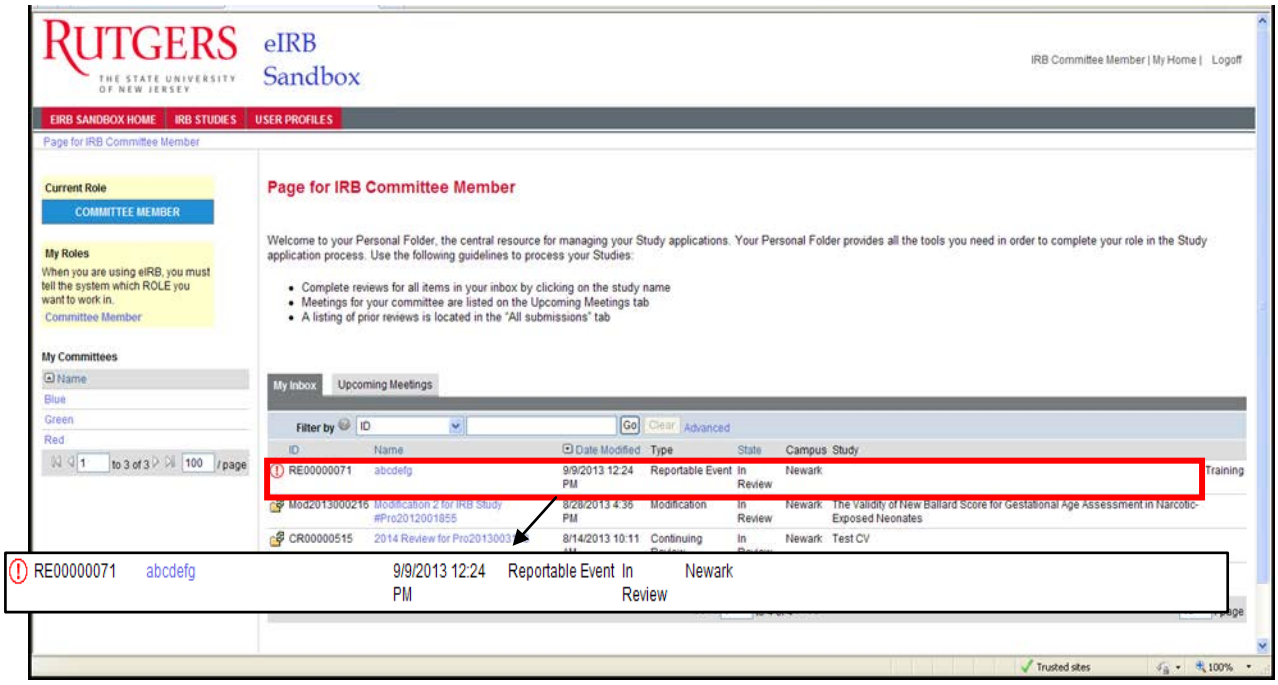



In the 'Modification Workspace', submit your review by clicking on the 'Submit Review' button then:

- Upload any documents
- Record any comments
- Select 'Review Motion'
- Check off 'Review Complete
- Select 'OK' to submit.

## Reviewing a Reportable Event

To review a reportable event, select the title of the study listed under 'My Inbox'.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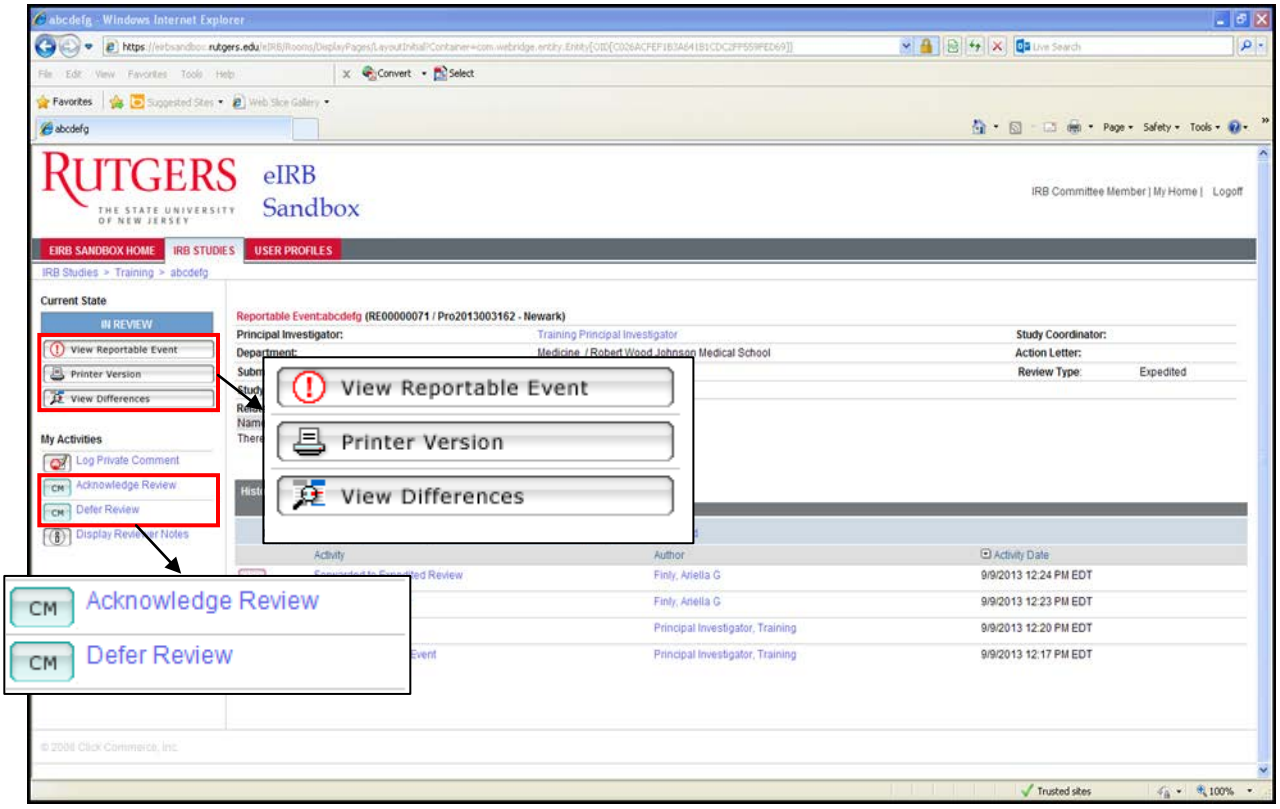
eIRB Sandbox
IRB Committee Member | My Home | Logoff
EIRB SANDBOX HOME
IRB STUDIES
USER PROFILES
Page for IRB Committee Member
Current Role
COMMITTEE MEMBER
My Roles
When you are using eIRB, you must tell the system which ROLE you want to work in.
Committee Member
My Committees
Name
Blue
Green
Red
Page for IRB Committee Member
Welcome to your Personal Folder, the central resource for managing your Study applications. Your Personal Folder provides all the tools you need in order to complete your role in the Study application process. Use the following guidelines to process your Studies:
Complete reviews for all items in your inbox by clicking on the study name
Meetings for your committee are listed on the Upcoming Meetings tab
A listing of prior reviews is located in the "All submissions" tab
My Inbox
Upcoming Meetings
Filter by
ID
Name
Date Modified
Type
State
Campus
Study
RE00000071 abcdefg 9/9/2013 12:24 PM Reportable Event In Review Newark
Mod2013000216 Modification 2 for IRB Study #Pro2012001855 8/28/2013 4:35 PM Modification In Review Newark The Validity of New Ballard Score for Gestational Age Assessment in Narcotic-Exposed Neonates
CR00000515 2014 Review for Pro2013003 8/14/2013 10:11 Continuing In Newark Test CV
Training
RE00000071 abcdefg 9/9/2013 12:24 PM Reportable Event In Review Newark

**! Note: Reportable Events are easy to recognize because their icon is an exclamation point as compared to other study states.**

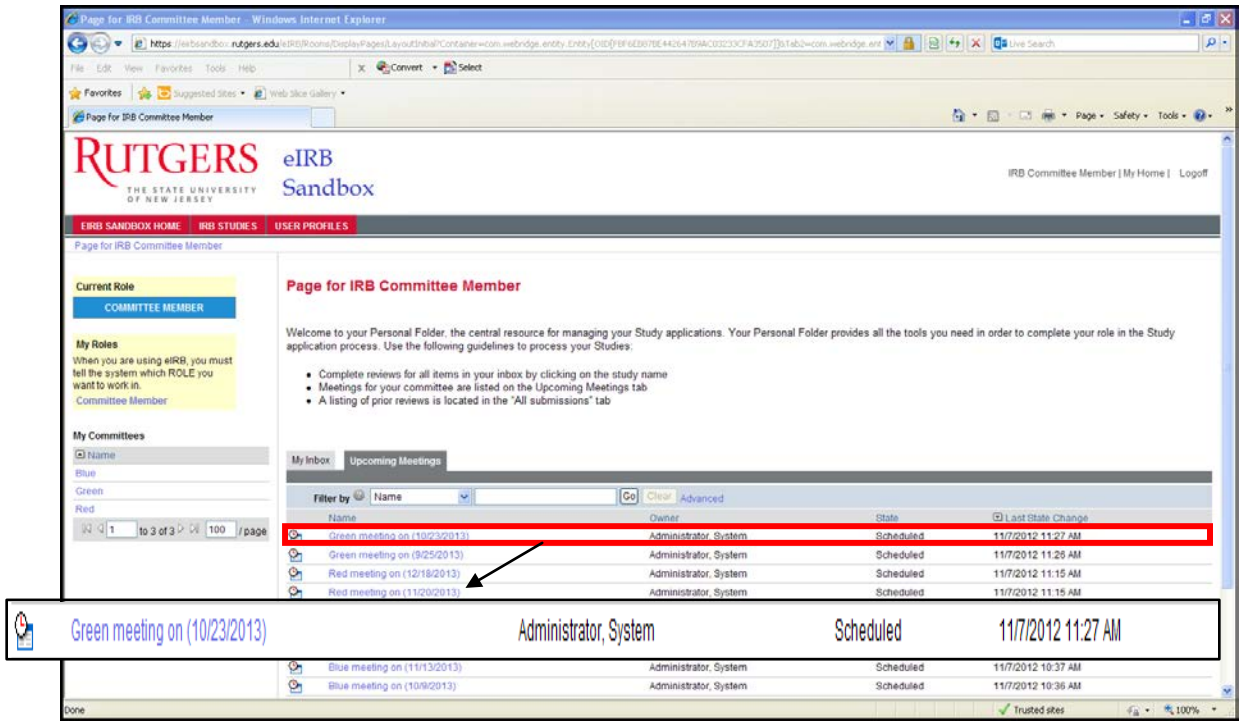


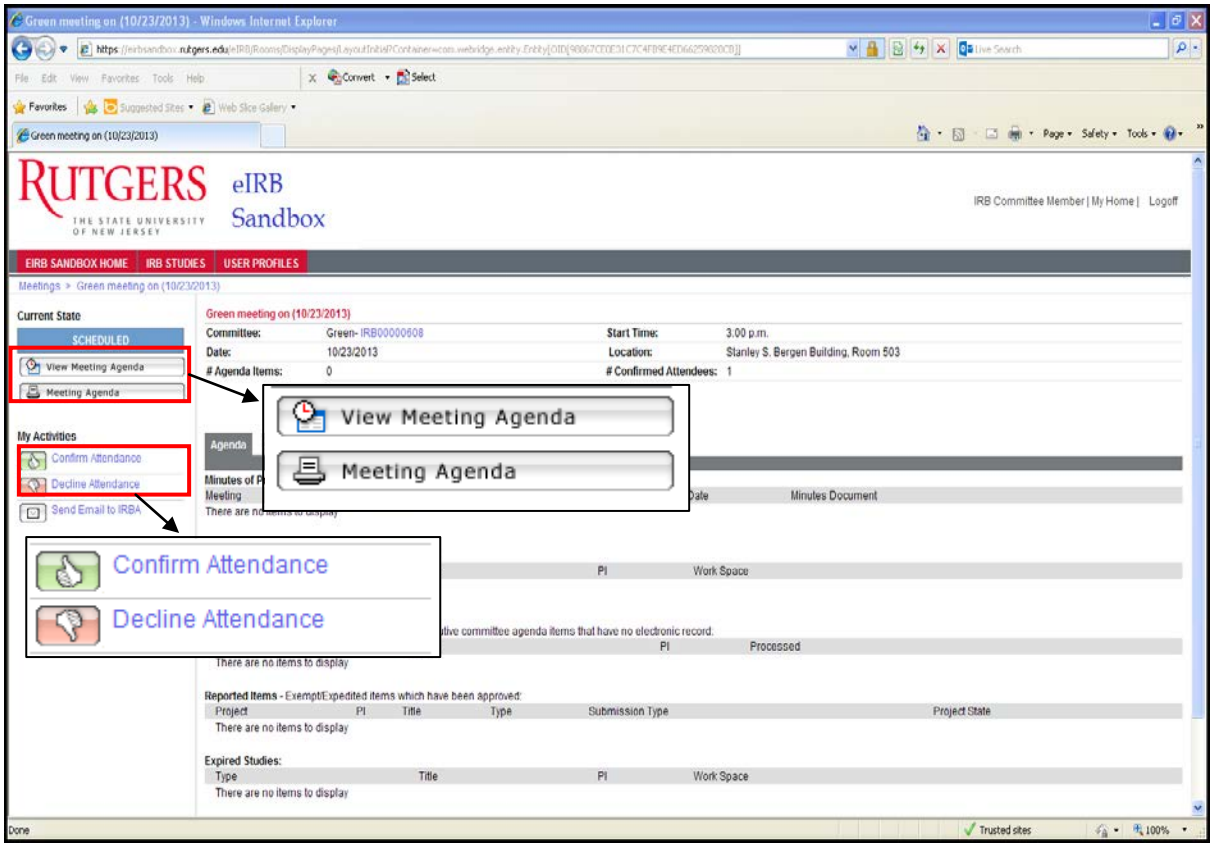

The process for reviewing a Reportable Event is the same as the previous submission examples.

- Decide whether to Acknowledge or Defer the Reportable Event
- View the Reportable Event by selecting 'View Reportable Event'
- 'Add' Reviewer Notes in the same manner as before within the smart-form application

## Reviewing an IRB Meeting Agenda

Each month, you will receive an email from eIRB indicating that the meeting agenda is ready to view. To view studies assigned to other reviewers, select the 'Upcoming Meetings' tab in the grey menu bar at the top of your 'My Home' page view. Select the name of the upcoming meeting you wish to view.






- You can ‘Confirm’ or ‘Decline’ your meeting attendance by selecting the appropriate button located on the left navigation pane.
- Select ‘View Meeting Agenda’ to open the smart form page of the agenda.

## Glossary

**Attachments**: Lists documents attachment to a study.

**Change Log**: Lists changes made to the initial application.

**Conditions**: Status of contingencies for the approval of the study.

**Current State**: Specifies where the study is in the IRB review process. Three possible study states include: In Review, Meeting in Progress, or In Revisions Review.

**Department Approvals**: Lists the department(s) that approved the study.

**eIRB Home**: Brings you back to the eIRB homepage.

**History**: List of all actions performed on this study submission.

**IRB Studies**: Lists all eIRB studies.

**Jump-To Menu**: A tool located at the top of a smart form in a project which enables users to navigate through the submission pages without having to search through pages unnecessarily.

**Logoff**: Ends your eIRB session.

**Modification**: The form which study staff completes indicating the proposed changes made to a Study.

**Modified Study**: A copy of an approved study where study staff has made actual changes to the IRB.

**My Activities**: Displays the actions that you can perform at this point in a study.

**Log Private Comment**: Allows you to add a comment or upload a document only viewable by IRB Staff and Committee Members.

**My Committees**: Provides a quick link to the IRB committees you serve on.

**My Home**: The default user page. Always takes you back to your personal workspace page.

**My Roles**: Shows your current role and lists multiples roles, if applicable. This section determines your access level and personal workspace**.**

**Navigation Pane**: The location in every workspace which holds all available activities for the study.

**Printer Version**: Opens a page to view an entire document that displays all sections in its entirety, and prints easily on most printers. The printer version view contains clickable links to certain study documents which opens in a new window. You cannot add reviewer notes to this version.

**Reviewer Notes**: Lists notes left by the reviewer.

**Reviews**: Lists assigned reviews for reviewer.

**Stamped Documents**: This section lists all IRB stamped documents. These PDF documents are watermarked with an IRB approval and expiration date.

**User Profiles**: Lists personal profile and contact information for eIRB members.

**View Differences**: Opens a page to view and compare changes made to the original application.

**View Study**: Opens smart-form applications and allows committee members to submit reviewer notes.

**Your name**: Access/Modify personal contact information. This tab also allows you to change your password.

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# IRB Determinations Guide

## Approved

☐ The IRB determines that based upon all applicable federal regulations, and a review of all submitted documents, the research may proceed without any conditions. An Approval notice will be issued at which time the research may be initiated or continued.

## Approval with Conditions

☐ At the time the IRB reviews and approves a research study, the IRB requires that before research can be, approved, the investigator make changes specified in the action letter/debriefing memo.

Examples:

- Submission of the signed Financial Disclosure Form
- Completion of CITI Training
- Revised Research Protocol
- Clarification of information provided in the application
- Revised language to be incorporated into consent documents
- Conflict of Interest Determination

**Note: <u>Application is not approved at this stage</u>.**

**<u>Applicability:</u>**

For this level of re-review, the clarifications/changes required are minor.

## Approved with Stipulations

☐ The IRB has approved the proposed research or changes as submitted with **stipulations**. Stipulations mandated by the IRB may prohibit the investigator(s) from conducting or initiating certain aspects of the study. Stipulations may only be removed by submitting required documents for review by the IRB.

Examples:

- Approval Notices
- Certificate of Confidentiality
- Letters of Agreement

**Note: Application is approved**.

## Approval Denied

☐ The IRB determines that based on all applicable federal regulations, the research cannot be approved. Research activities may not be conducted at Rutgers or by Rutgers employees or agents.

## Tabled

☐ The IRB determines that there are major substantive issues that must be resolved or there is a lack of sufficient information about the research to proceed with its review. The IRB review may not proceed and approval may not be granted until the convened IRB has approved a revised application incorporating all requested information or changes.

**Applicability**

For this level of review, the changes required are major and complex; the protocol is judged to have serious problems or lack sufficient information for the committee to appropriately assess the risks to subjects..

## Deferred

☐ The IRB is not able to make all the determinations due to (a) lack of sufficient time for discussion, (b) because it feels it lacks the required expertise, or (c)an Expedited Reviewer does not feel it meets the criteria for Expedited Review. At that time the study must be

(a) reviewed at a later convened meeting providing sufficient discussion time

or

(b) reviewed by the campus Executive IRB committee for sufficient expertise

or

(c) reviewed by a fully convened IRB committee

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**Full Board Committee Actions or Requests**

## Administratively Closed

☐ This is an administrative process by which a previously approved study has expired, and the principal investigator has not submitted a *Continuing Review* application or a *Final Closure*, indicating study completion.

## Suspended

☐ The IRB determines that, in the best interest of human subjects, some or all aspects of the research must cease temporarily. This may occur when a study is under investigation due to compliance issue(s), following a protocol deviation, adverse event, or unanticipated event involving risks to human subjects or others.

## Request Changes/ Clarifications

☐ At the time when the IRB reviews and approves a research study (or proposed changes to a previously approved research study), the IRB requests modification of the application at which time the investigator must either

(a) provide clarifications to specific questions,

or

(b) submit requested changes to revised documents, such that, based on the assumption that these changes or clarifications are satisfactory, the IRB is able to make all of the determinations required for approval

## No further action required

☐ The IRB Executive committee determines that no further changes, revisions or corrections are required on the part of the investigator or the IRB committee.

## Action required

☐ The IRB Executive committee determines that further changes, revisions or corrections are required on the part of the investigator or the IRB committee.

## Acknowledged

☐ Upon receipt of a reportable event, the IRB reviews and issues confirmation of the submission.

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# HSSP & Campus IRB Office Locations and Contact Information

| | |
|---|---|
| **Website: http://rbhs.rutgers.edu/hsp/**<br><br>**Human Subjects Protection Program**<br>Office: 973-972-1149<br>FAX: 973-972-1598<br>65 Bergen Street, SSB 507<br>Newark, NJ 07107 | **Newark IRB**<br>Office: 973-972-3608<br>FAX: 973-972-0906<br>65 Bergen Street, SSB 511<br>Newark, NJ 07107<br>email: IrbNWK@ca.rutgers.edu |
| **New Brunswick IRB**<br>Office: 732-235-9806<br>FAX: 732-235-9810<br>390 George Street<br>Suite 700<br>New Brunswick, NJ 08901<br>email:<br>IrbNB@ca.rutgers.edu | **Stratford IRB**<br>Office: 856-566-2712<br>FAX: 856-566-7195<br>40 East Laurel Road,<br>UEC 1106<br>Stratford, NJ 08084 |